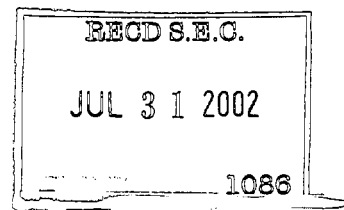




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2002 ANNUAL REPORT

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New opportunities

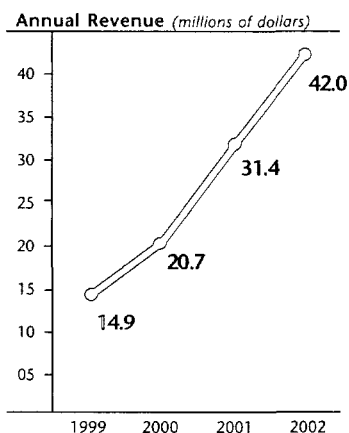
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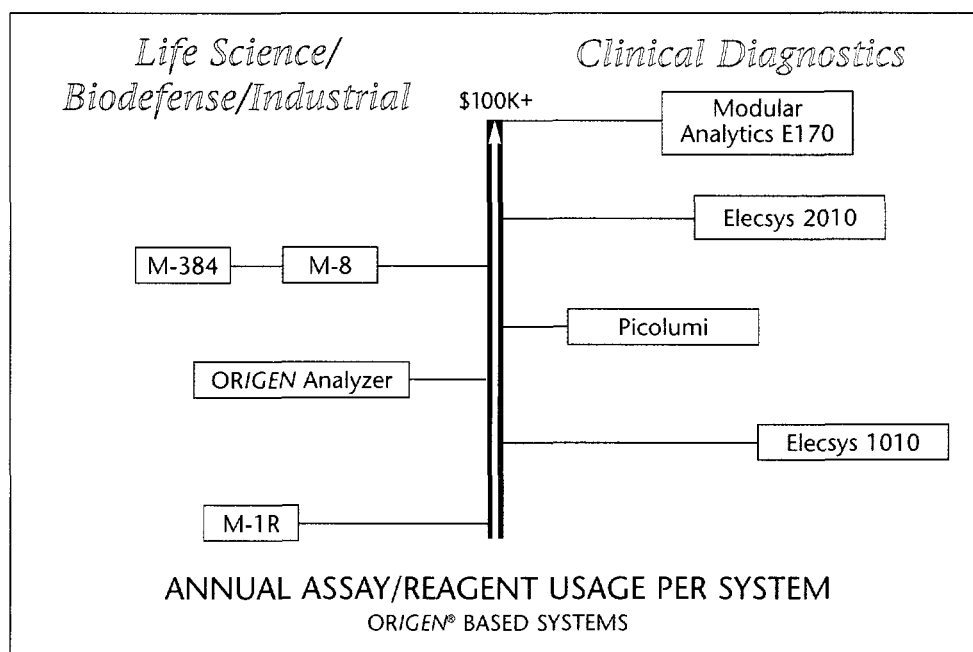
Growth and great global opportunities.



Over the past three fiscal years, revenue has increased at a compound annual rate of over 40%.

In February 2002, the U.S. District Court issued a final order of judgment against Roche Diagnostics, a division of F. Hoffman LaRoche, which awarded IGEN \$505 million in damages; confirmed IGEN's right to terminate the Roche license; and ordered Roche to grant IGEN a license to certain improvements, including the Roche Elecsys® product line.

As a result, we are free to pursue new partnerships and new marketing opportunities. We are taking steps to maximize the value of our technology for customers and shareholders. And, we continue to grow through the development of new diagnostic products that use IGEN consumables, an ongoing revenue stream for the company.



IGEN develops and markets biological detection systems based on its proprietary *ORIGEN* technology, which provides a unique combination of sensitivity, reliability, speed and flexibility. *ORIGEN*-based systems are used in a wide variety of applications, including clinical diagnostics, pharmaceutical research and development, life science research, and industrial testing for food safety and quality control. These systems are marketed by IGEN and its licensees and/or distributors—Roche Diagnostics, BioMerieux, Eisai, Sumitomo Corp., Sanko Junyaku Co. Ltd and Reactionlabs Oy.

PATH *IGEN*TM

***E. coli* 0157 Test**

Lot No.: 32179

Exp. Date: 7/4/03

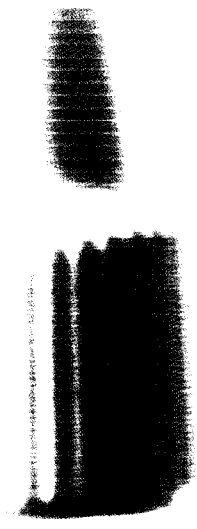
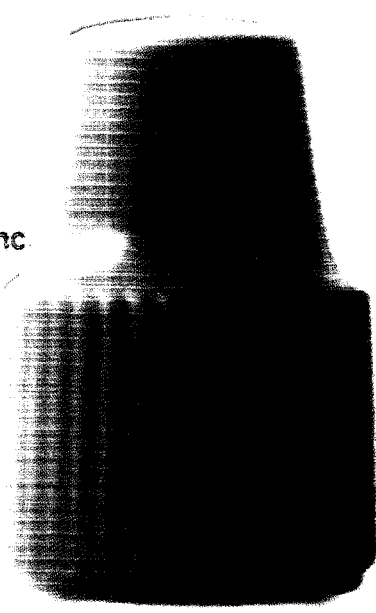
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Storage: 2-8°C

NOT FOR HUMAN USE

IGEN[®] International, Inc.
16020 Industrial Dr.
Gaithersburg, MD 20878

Covered by one or more U.S. Patents
Nos. 5,281,033; 5,283,033; and 5,714,000
Additional patents pending



To Our Shareholders:

A momentous year for IGEN.

Our progress encompassed 34% revenue growth over last year, new product approvals and market introductions, expanded business opportunities in biodefense testing, financings for our near-term growth, and a major court victory in our litigation with Roche Diagnostics. There are tremendous opportunities before us to build on this progress, and we are diligently examining them to determine the course that is in the best interests of all shareholders.

Opportunities from Success in the Roche Litigation

IGEN had a tremendous victory in the Roche litigation. The court judgment was a clear and strong affirmation of our position. This judgment includes IGEN's right to terminate the Roche license; IGEN's right to improvements, which include the entire Elecsys 1010 and 2010 instruments, the E170 system, all of the assays that are used on those instruments and PCR for genetic testing; and a monetary award of \$505 million.

With the combination of termination, improvements and the monetary award, IGEN and its potential new partners, collaborators and distributors have the opportunity to become serious competitors in \$20+ billion dollar market segments. These markets include clinical immunodiagnostic and molecular probe tests for hospitals, reference labs and various point-of-care sites, such as clinics, emergency rooms, intensive care units, physicians' offices and even the home. It also includes the testing in life science research and testing for food, water, soil and airborne pathogens that might threaten the national health.

IGEN has the product pipeline, based on the ECL technology, to do it. Several years ago, the lone ECL product was the *ORIGEN* Analyzer system (the 1.5 model). Today, instrument systems on the market or very close to launch include:

- *ORIGEN* Analyzer (1.5 model)
- M-8 and the new M-384
- M-1
- Elecsys 2010 and 1010 and the E170 (Roche)
- Picolumi (Eisai)
- Sector HTS and Sector PR (Meso Scale Diagnostics)

There's also a catalog of several hundred applications that use consumable reagents and over 50 clinical assays.

New Product Opportunities

During the past year, we advanced IGEN's product portfolio for life science, food and biodefense testing. New products introduced include the M-SERIES 384 Analyzer, a next-generation system for life science that adds product features to enhance the M-8 system. IGEN also launched the *INTELLIGENT* system to the industrial food testing market, marking the first commercial application of the M-1 product line. The M-1 product line has multiple applications and will serve as the basis for instruments in additional markets, including life science, clinical diagnostics and biodefense.

As both military and civilian homeland security has become increasingly important this year, IGEN's products have been identified as important contributors. Early in 2001, IGEN and the U.S. Army signed a Cooperative Research and Development Agreement (CRADA) to develop tests for food/water/environmentally borne toxins. These tests were targeted to be part of the U.S. Army's role in protecting American troops from diseases caused by biological agents. Recently, an initial agreement to sell instruments and reagents to the Department of Defense was concluded. These products are being deployed to various DOD laboratories for detection of toxins in environmental samples. Expanding on this initial arrangement, DOD has begun purchasing IGEN's PATH/IGEN® tests and instrumentation to protect U.S. troops from foodborne illnesses. This is a beginning of what we hope will be a long-term relationship with the DOD, and we are excited about the spectrum of opportunities this creates for IGEN.

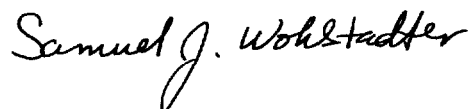
Financial Opportunities

IGEN's financial status is the strongest in its history. During the year ended March 31, 2002, IGEN's revenue increased 34% to a record \$42 million. This represents a cumulative annual revenue growth rate over the last three years in excess of 40%. We completed our fiscal year 2002 with cash and cash equivalents of approximately \$75 million and total assets of \$106 million. Together with access to additional capital, this enhances our ability to continue advancing our business plans, including if necessary, completion of the Roche litigation process through the end of their appeal. Also, our strategic and financial advisory teams of Lehman Brothers and Goldman Sachs can assist in the evaluation of alternative business opportunities.

Looking Ahead

We have a first-class group of exceptionally talented employees and ownership of the broadest and best technology platform in the diagnostic industry. Together we saw the ultimate potential of the proven ORIGIN technology platform and its power to sustain superior organic growth. With multiple opportunities before IGEN, there are challenges to be met. IGEN is focused on meeting these challenges. We will concentrate our energies on expanding the business directly and with new collaborators. This process will not happen overnight, but we now have additional open avenues to maximize shareholder value.

Sincerely,



Samuel J. Wohlstadter
Chairman and Chief Executive Officer



Richard J. Massey, Ph.D.
President and Chief Operating Officer

July 18, 2002

Important Note to Investors: This Annual Report contains forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about trends in financial or operational performance, the potential utility and performance of ORIGIN technology, market growth forecasts, litigation, new product plans, and alliances to explore development of new products. Actual results might differ materially from these statements due to risks and uncertainties, including those associated with decisions made by IGEN's partners and customers, the impact of competitive products and pricing, market acceptance of new products, market conditions, and enforcement of IGEN's intellectual property rights. A more detailed description of risks applicable to IGEN appears in the Form 10-K, incorporated in this Annual Report, and in other documents filed with the Securities and Exchange Commission and available on request from the company. IGEN disclaims any intent or obligation to update these forward-looking statements.

Focused on meeting
the challenges.

IGEN
INTERNATIONAL

Form 10-K

SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES ACT OF 1934

For Fiscal Year Ended March 31, 2002

Commission File Number 0-23252

IGEN International, Inc.

(Exact name of Company as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation or organization)

94-2852543

(IRS Employer
Identification No.)

16020 INDUSTRIAL DRIVE, GAITHERSBURG, MD

(Address of principal executive offices)

20877

(Zip Code)

301-869-9800

(Company's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: NONE

Securities registered pursuant to Section 12(g) of the Act: Common Stock \$0.001 par value
(Title of Class)

Indicate by check mark whether the Company (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Company was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained to the best of the Company's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. X

The aggregate market value of the voting and non-voting equity held by non-affiliates of the Company as of June 17, 2002, computed by reference to the closing sale price of such stock quoted on the Nasdaq National Market, was approximately \$628,877,000.

The number of shares outstanding of the Company's Common Stock as of June 17, 2002 was 23,215,738.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K. Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Company's definitive Proxy Statement relating to its Annual Meeting of Shareholders to be held on August 28, 2002.

PART I

In addition to historical information, this Form 10-K contains forward-looking statements within the meaning of the "safe harbor" provision of the Private Securities Litigation Reform Act of 1995. Reference is made in particular to statements regarding the markets and potential markets, and market growth, for diagnostic products, potential impact of competitive products, the Company's expectations regarding the level of anticipated royalty and revenue growth in the future, the potential market for products in development, financing plans, the outcome of litigation, the description of the Company's plans and objectives for future operations, assumptions underlying such plans and objectives, the need for and availability of additional capital and other forward-looking statements included in Item 7—"Management's Discussion and Analysis of Financial Condition and Results of Operations" ("MD&A"). The words "may," "should," "will," "expect," "could," "anticipate," "believe," "estimate," "plan," "intend" and similar expressions have been used in this document to identify forward-looking statements. We have based these forward-looking statements on our current views with respect to future events and financial performance. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties which could cause actual results to differ materially from those described in the forward-looking statements. In particular, careful consideration should be given to cautionary statements made in Item 7—"Management's Discussion and Analysis of Financial Condition and Results of Operations" and in Item 1—"Business" under the heading "Risk Factors." IGEN disclaims any intent or obligation to update these forward-looking statements.

ITEM 1. BUSINESS

Summary

We develop and market products that incorporate our proprietary electrochemiluminescence (ORIGEN®) technology, which permits the detection and measurement of biological substances. We believe that ORIGEN offers significant advantages over competing detection methods by providing a unique combination of speed, sensitivity, flexibility and throughput in a single technology platform. ORIGEN is incorporated into instrument systems and related consumable reagents, and we also offer assay development and

other services used to perform analytical testing. Products based on our ORIGEN technology currently address the following worldwide markets:

- Life Science—drug discovery and development, performed by pharmaceutical and biotechnology companies, universities and other research organizations;
- Clinical Testing—*in vitro* diagnostic testing of patient samples to measure the presence of disease and monitor medical conditions. This testing is performed at facilities, such as central hospital and clinical reference laboratories, and at other locations, including sites closer to where patient care is delivered. These sites include clinics, emergency rooms, intensive care units and physician offices; and
- Industrial Testing—the testing of food and environmental samples for safety and quality assurance purposes, products for fighting bioterrorism, as well as agricultural and animal health testing.

We and our corporate collaborators have commercialized multiple product lines to serve these markets. We estimate that approximately over 8,000 ORIGEN-based systems have been sold or placed with customers. These sales and placements have been made predominantly through our license arrangement with Roche Diagnostics GmbH ("Roche"), the world's leading provider of clinical diagnostic products. Roche has adopted ORIGEN as the integral technology for its Elecsys immunodiagnostic product line. Roche has a license to commercialize the ORIGEN technology solely for central hospital and clinical reference laboratories and blood banks. For a discussion of the Roche litigation, see ITEM 3, "Legal Proceedings."

The M-SERIES™ System, our product line for use by pharmaceutical and biotechnology companies in drug discovery and development, may be used in all phases of drug discovery, including (1) validating targets identified through genomics, (2) screening of large numbers of compounds generated through combinatorial chemistry, (3) re-testing and optimization of lead compounds, and (4) clinical trial testing of drug candidates. We believe the M-SERIES System provides a number of advantages relative to other drug discovery technologies, including enhanced sensitivity and greater ease and speed of assay formatting. These features are designed to enable our customers to test new biological targets against

potential drug compounds with higher levels of accuracy and specificity and may perform highly sensitive tests more quickly and with less cost. This should permit a drug candidate to move more rapidly into the later stages of drug development and ultimately into the market.

The M-SERIES System is the first product that features our electrochemiluminescence module, which we have trademarked as TRICORDER®. The TRICORDER, which resulted from our extensive research and development efforts, is a self-contained, analytical operating system. By combining all of the features necessary to perform ORIGIN-based testing in a single compact module, the TRICORDER provides a relatively simple-to-use, highly accurate and cost-effective system. The TRICORDER's modular nature is expected to reduce the development time and cost required to incorporate ORIGIN technology into future diagnostic and analytical instruments. We believe that the TRICORDER, through its flexibility as a detection tool and its modular nature, will be the core component for additional products that we plan to develop.

Our M-SERIES customers include many of the major pharmaceutical and biotechnology companies in the United States and Europe. We offer our customers the option of buying M-SERIES Systems or renting them under reagent purchase plans. Under either option, our customers typically make commitments for purchases of proprietary reagents. We also provide custom assay development services based on our existing library of more than 300 assays. We market the M-SERIES System through our sales, marketing and applications team dedicated to the life science market.

We have also applied our ORIGIN technology to the rapidly growing market for the detection of food and water disease causing pathogens, as well as for bio-defense, the detection of microbes, toxins and toxic agents that may pose a military or public health threat. We have begun commercializing our first products for this market, the PATHIGEN® panel of tests for Salmonella, Campylobacter, Listeria and *E. Coli* O157, which are sold primarily as a quality control test method to food producers, food processors and contract laboratories for the food industry. The *E. Coli* test, for example, is significantly more sensitive than any other test on the market and we believe it offers unprecedented precision and rapid results in detecting this dangerous strain of the food-borne pathogen.

In addition, our Salmonella test was recently approved by the National Poultry Improvement Plan as the first rapid method for the detection of Salmonella in live poultry.

Our executive offices are located at 16020 Industrial Drive, Gaithersburg, Maryland 20877.

ORIGIN Technology

ORIGIN is a proprietary technology based on electrochemiluminescence. ORIGIN permits the detection and measurement of a biological substance within a given sample. It works by labeling the targeted substance within a sample using a compound and binding the newly labeled substance to magnetizable beads. The beads can then be separated from the rest of the sample using a magnet. When this newly labeled substance is stimulated, the label emits light at a particular wavelength. The light emission can be measured with a high degree of accuracy. The level of intensity of the light emitted depends on how much of the label is present, which in turn is determined by how much of the targeted substance is present for the label to attach itself to. Thus, the light emissions permit the accurate detection and measurement of the targeted substance. ORIGIN technology provides a single basic format that can be used to conduct a multitude of tests, including immunodiagnostic tests, nucleic acid probe tests and clinical chemistry tests. The ORIGIN technology is protected by numerous patents in the United States and internationally.

We and our licensees are using the ORIGIN technology to develop and commercialize analytical systems that offer many advantages over current detection technologies. We believe that ORIGIN technology offers a unique combination of improved speed, sensitivity, flexibility and output relative to existing technologies. ORIGIN technology also generally lowers the cost of diagnostic procedures by reducing the number of steps required in preparing a sample for testing. Because the ORIGIN system directly measures electrochemiluminescence, and does not require the use of enzymes in the detection process as is common in competing systems, the ORIGIN system provides a simplified and more stable format that can be used to test a broad range of substances. The ORIGIN-based systems can be automated to provide in a uniform format a large number of immunoassay, nucleic acid probe and clinical chemistry tests. The essential component of an ORIGIN-based system is the flow cell, which

contains a magnet to separate the labeled substance from the sample being tested, and a light detector to measure the electrochemiluminescence. The ORIGIN flow cell has been designed so that it can be incorporated into a variety of instruments, ranging from large central laboratory random-access systems to small batch systems.

The major features and benefits of proprietary ORIGIN-based systems are:

- *Simple Testing Format*: reduces time and labor in performing a test or series of tests. Complete automation of testing process possible.
- *Flexibility*: enables a single instrument to perform immunodiagnostic tests on large and small molecules and to perform DNA and RNA tests.
- *Cost*: reduces costs per test by minimizing the amount of expensive reagents needed.
- *Speed*: reduced time from assay set-up to detection produces rapid results. Enables high sample throughput.
- *Sensitivity*: allows detection of targeted specimens at very low concentrations.
- *Precision*: provides highly-reproducible measurements.
- *Label Stability*: extends the shelf-life of the reagent that contains the label used in testing. Improves measurement accuracy.

ORIGIN-Based Products and Markets

We believe that our ORIGIN technology is well-suited for the development and commercialization of families of instruments that can be used in all of our target markets. The technology should permit virtually all immunodiagnostic and nucleic acid tests to be performed on similar instrumentation using the same detection method.

The following table summarizes ORIGIN-based products and development programs.

Market	Product	Customer Application	Status	Commercial Rights
Life Science Market	M-SERIES (M8 & M384 Analyzer and Reagents)	Drug Discovery/Development	Product Sales	IGEN
	M-SERIES (M-1 Research Analyzer)	Drug Discovery/Development	Pre-Launch	IGEN
	ORIGIN Detection System and Reagents	Drug Discovery/Development	Product Sales	IGEN
	Cell Culture Reagents	Research Biologicals	Product Sales	IGEN
	NucliSens/NASBA QR	Nucleic Acid Probe Tests	Product Sales	BioMerieux
	Sector HTS/Sector PR	High Throughput Drug Discovery/Development	Pre-Launch/Beta	Meso Scale Joint Venture
Clinical Testing Market				
Central Hospital/Clinical Reference Laboratory Systems	Elecsys 2010	Immunodiagnostic Tests	Product Sales	Roche
	Elecsys 1010	Immunodiagnostic Tests	Product Sales	Roche
	MODULAR/E170	Immunodiagnostic Tests	Product Sales	Roche
	NucliSens/NASBA QR	Nucleic Acid Probe Tests	Product Sales	BioMerieux
	Picolumi	Immunodiagnostic Tests (Japan)	Product Sales	Eisai (Japan)
Patient Care Systems	Elecsys 2010/1010	Physicians' Office Lab Immunodiagnostic Tests	Product Sales	IGEN ⁽¹⁾
	M-SERIES (M-1 Clinical Analyzer)	Portable Physicians' Office Lab/Hospital Immunodiagnostic Tests	Development	IGEN
	Home Self-Testing	Health Screening and Monitoring	Research	IGEN

Market	Product	Customer Application	Status	Commercial Rights
Industrial Markets	PATHIGEN Panel of Tests (ORIGEN Detection System)	Detection of Food and Beverage Contaminants	Product Sales	IGEN
	M-SERIES (M-1 Analyzer)	Detection of Food and Beverage Contaminants and Biological Toxins	Pre-Launch	IGEN

⁽¹⁾ IGEN is currently servicing customers pursuant to court judgment issued in the litigation described in ITEM 3—"Legal Proceedings."

Life Science Products and Market

The life science market focuses on providing products and services for the discovery and development of new drugs. Our commercialization efforts in this market center on the M-SERIES System and the ORIGEN Detection System.

Advances in the field of combinatorial chemistry, which is based on the effects of combining different compounds to make potentially new drugs, and in the field of biotechnology have revolutionized drug discovery. Pharmaceutical and biotechnology companies have dramatically expanded their libraries of potential drug candidates. Researchers have completed sequencing of the human genome, which has greatly increased scientists' understanding of how diseases work and the causes of disease, which in turn should provide novel targets for fighting disease.

In order to exploit these advances, pharmaceutical and biotechnology companies are re-engineering their drug development processes. An example of this is the use of automation and the latest advances in technology to accelerate the screening of existing drug compounds against the disease targets of interest. Researchers are challenged to develop new drug screening procedures that are faster and more efficient while reducing costs and processing larger numbers of samples.

After identifying disease targets and synthesizing chemical compounds, researchers attempt to find compounds that are drug candidates. This drug discovery process involves developing the test, or assay, to determine whether a particular compound has the desired effect on a target and then screening compounds using that assay. Compounds of interest from the screening process become drug candidates, which undergo further testing as part of "lead optimization." These drug candidates are then subjected to pre-clinical and clinical trials before becoming a drug.

M-SERIES System. We believe that the need of pharmaceutical and biotechnology companies to rapidly identify therapeutic targets; screen thousands of compounds per day against those

targets; and then optimize the leads has created new opportunities for our ORIGEN technology systems in the pharmaceutical and biotechnology industry. The M-SERIES Systems, based on the TRICORDER, build on the applications of the ORIGEN Detection System and provide simultaneous processing of multiple samples using ORIGEN assays. The first M-SERIES System is the M8 Analyzer, which is compatible with multi-well microplates that are commonly used in drug discovery and development laboratories. The M8 Analyzer has been updated and is named the M-SERIES 384 Analyzer. It is in the process of being introduced to the market with new features. Both systems can be fully integrated with many existing automation and robotic systems and are designed to enable researchers to test new biological targets against potential drug compounds with higher levels of accuracy and specificity. They may also perform highly sensitive tests more quickly and with less cost. This may permit a drug candidate to move more rapidly into the later stages of drug development, clinical trials and ultimately into the market.

We believe that the sensitivity and accuracy of the M-SERIES System create advantages over many competitive detection technologies. The M-SERIES System allows the user (1) to quickly adapt the ORIGEN technology to develop and then perform the specific, desired assays, compared to the longer periods required by other existing competing technologies, (2) to reduce the use of rare components, such as proprietary compounds, antibodies or clinical trial samples, that must be used to run assays and (3) to be more confident in the positive and negative results the tests produce. Our expertise in developing assays allows us to assist customers in determining whether a proposed assay is feasible and to assist with the development and performance of assays that comply fully with the U.S. Food and Drug Administration's (FDA) Good Manufacturing Practices (GMP).

Our M-SERIES customers include many of the major pharmaceutical and biotechnology companies in the United States and Europe. In addition to the M-SERIES Analyzers we sell or

place, we typically receive commitments from our customers for purchases of proprietary reagents. We also offer M-SERIES Analyzer users custom assay development services based on our existing library of more than 300 assays. We market the M-SERIES Analyzer directly through our sales, marketing and applications team dedicated to the life science market.

The second product in the M-SERIES family is the *M-1*, which is in final pre-launch development. The *M-1* is being designed as a smaller and lower cost M-SERIES system for use in drug discovery and development, as well as for basic biology research such as the study of general biological processes, proteomics and the understanding of the molecular basis of disease. In addition to pharmaceutical and biotechnology researchers, the *M-1* may be used by scientists at academic and government research institutions. Academic customers typically work from small research grants and a lower priced single detector system that works with the standard microplate format is expected to be an alternative to the use of radioisotopic assays or less sensitive ELISA based methods. ORIGIN technology, with its mix and read assay format and high sensitivity should allow researchers to perform multiple experiments more quickly.

ORIGIN Detection System. Our strategic links with pharmaceutical and biotechnology companies and with customers in government and academic research centers were initially forged with the launch of the ORIGIN Detection System. The ORIGIN Detection System is the precursor to the M-SERIES System and established ORIGIN as a powerful detection technology for applications in life science research. Some of these customers are performing research in areas that are key to our strategic growth. The ORIGIN Detection System has been important for our developments with the U.S. military and the application of ORIGIN technology to bio-defense.

Clinical Diagnostic Products and Market

One of the markets that we have and will continue to target by developing and marketing products and services based on our ORIGIN technology is the clinical diagnostic market. The clinical diagnostic market utilizes *in vitro* diagnostic testing, which is the process of analyzing blood, urine and other samples to screen for, monitor and diagnose diseases and other medical conditions or to determine the chemical and microbiological constituents of the samples.

This market is composed of various areas of clinical diagnostic testing, including testing by central hospital laboratories and clinical reference laboratories, as well as testing at satellite hospital laboratories and at or near patient care centers.

Hospital/Reference Laboratory Systems. One of the significant applications of our ORIGIN technology is in large, highly automated clinical immunodiagnostic systems used in central hospital laboratories, clinical reference laboratories and blood banks. These laboratories constitute the vast majority of the clinical diagnostic market today. To serve these laboratories, systems must be able to perform a wide variety of immunodiagnostic tests on a large number of samples reliably, cost-effectively and quickly. We and our licensees believe that systems based on the ORIGIN technology are well-suited to serve this market and may surpass other systems currently available in central hospital laboratories, clinical reference laboratories and blood banks in terms of speed, cost effectiveness and ease of use.

Roche, one of the companies that licenses our technology, presently sells three ORIGIN-based immunoassay systems for the central hospital and clinical reference laboratory markets: the Elecsys 1010, Elecsys 2010 and the Modular E170. The Elecsys 2010 is designed to perform multiple screenings in a random-access mode, while simultaneously handling tests performed on clinical samples for which immediate results are needed, without interfering with the system workflow. The Elecsys 2010 is designed so that it can be integrated with Roche's clinical chemistry systems. The Elecsys 1010 is a system designed for central hospital and clinical reference laboratory customers that have a lower output requirement. Roche has also developed a third instrument system, the MODULAR/E170, which incorporates ORIGIN technology. The E170 is part of Roche's new MODULAR system that allows laboratories to create customized workstations and has the features of the existing Elecsys line together with expanded throughput capabilities.

Roche presently offers a panel of approximately 50 screening tests or assays, with the Elecsys and E170 systems, including assays for infectious diseases, anemia, cancer, heart attacks, thyroid disease and fertility/pregnancy. Roche continues to develop additional assays that are expected to be introduced to the market in the future. We continue to work with Roche to develop assays, for which Roche reimburses us a portion of our development costs.

See ITEM 3—"Legal Proceedings" for a description of our litigation with Roche.

Patient Care Systems. We are independently developing ORIGIN-based products that can be used to perform immunodiagnostic tests and chemistry tests outside of central hospital laboratories and clinical reference laboratories. This market includes patient care centers such as physicians'

offices, ambulatory clinics, hospital emergency rooms, surgical and intensive care units, hospital satellite laboratories, and nurses' stations. Physicians, patients and third-party payers have created a demand for bringing laboratory testing closer to the patient in order to provide the medical practitioner with faster results and, in turn, prompt feed-back to the patient. Most immunodiagnostic systems for individual physicians and group practices have had limited market penetration because of the lengthy turnaround time for test results, the need for skilled labor in performing the tests and the high cost of tests. We believe that the emergence of simple and more accurate and cost-effective diagnostic products is shifting the site of *in vitro* diagnostic testing from clinical reference and central hospital laboratories to alternative sites.

We believe that significant demand exists for clinical diagnostic products that reduce turnaround time and cost. Our patient care system is being designed to create tests that can provide accurate results to a physician rapidly, thereby permitting the physician to make a more timely decision regarding the patient's course of treatment.

The ORIGIN technology permits development of a system that is compact and simple to operate at a low cost per test and the initial clinical ORIGIN-based system being developed by the Company is utilizing the TRICORDER product platform currently used in the life science market. The broad menu of immunoassays that we, and companies working with us, developed for the first generation of ORIGIN-based products can be performed on, and are expected to be available for use with, TRICORDER-based systems. We are currently exploring collaborative business arrangements to accelerate the commercialization of TRICORDER-based products for multiple point-of-care applications.

We presently distribute clinical assays to approximately 60 physicians' office laboratories in the United States that utilize Roche's Elecsys systems. Under the final order of judgment issued in our litigation with Roche, the Court enjoined Roche from marketing, selling, or distributing its Elecsys products outside of Roche's licensed field of use, including to physicians' office laboratories (POL's). We and Roche signed an agreement under which all of Roche's POL customers in the United States were transferred to us, and Roche provides us with reagent supply for these customers pending final resolution of the litigation.

Industrial Products

We are seeking to develop further, either independently or with others, ORIGIN-based products for use in food and water quality assurance programs and agricultural and animal

health testing. We believe that our ORIGIN-based technology and the reagents employed to run tests, together with an easy to use, low-cost, instrument platform, such as the M-1 System under development, should be well-suited for these market applications.

We have recently commenced sales of our PATHIGEN panel of food pathogen tests. This panel includes tests for *E. Coli* O157, Salmonella, Listeria and Campylobacter. These tests are used as a quality control method for testing food and beverage products, such as the meat used in hamburger, for the bacteria that have caused numerous outbreaks of gastrointestinal and kidney-related disease worldwide. The PATHIGEN tests are semi-automated and create a permanent record of test results. According to published studies by the USDA and an independent analytical laboratory in the United Kingdom, the PATHIGEN *E. Coli* O157 test is significantly more sensitive than conventional tests commonly used to screen food. Major food and beverage producers, as well as contract testing laboratories, could become primary users of the PATHIGEN test panel. The major advantage of the PATHIGEN tests are their ability to perform in complex samples, like hamburger meat, in less time, and with greater sensitivity than other available methods. Our PATHIGEN tests offers food producers the ability to efficiently test many more food samples than with other currently available methods.

We have also expanded our ORIGIN-based product offering to address bio-defense, or the detection of microbes, toxins, and toxic agents that might pose a military or public health threat. ORIGIN-based tests developed by researchers in the U.S. Army are being used as a bio-defense detection method. We believe there will be an increasing opportunity for use of our ORIGIN technology as a bio-defense tool in military organizations around the world, as well as in public health. We plan to further develop ORIGIN-based products for this emerging market.

Collaborations

We have entered into collaborations with established diagnostic and pharmaceutical companies. These collaborations have provided us with \$84 million in license fees over an eight-year period and product development and marketing resources. In addition, we receive ongoing royalties from collaborators' product sales.

For the three fiscal years ended March 31, 2002, 2001 and 2000 revenue from corporate collaborators, which is represented as product-based royalty income and contract revenue, totaled \$27.5 million (65%), \$20.4 million (65%) and \$12.9 million (63%), respectively.

Roche Diagnostics GmbH. In 1992, we entered into a contract with Roche Diagnostics GmbH (then known as Boehringer Mannheim GmbH), the largest worldwide manufacturer of diagnostic equipment and supplies, to commercialize ORIGIN-based clinical immunodiagnostic and nucleic acid probe systems. From fiscal year 1992 through fiscal year 2002, we generated a total of approximately \$118 million in license fees, royalties and assay development fees from Roche. Roche currently markets three ORIGIN-based systems together with a test menu of approximately 50 different assays, including tests for infectious diseases, anemia, cancer, heart attacks, thyroid disease and fertility/pregnancy. Roche has placed or sold approximately 8,000 Elecsys and E170 systems worldwide.

In 1997, we filed a lawsuit in Maryland federal court against Roche Diagnostics and in February 2002, the Court issued a final order of judgment against Roche. See ITEM 3—"Legal Proceedings."

We recorded royalty income from the Roche agreement of \$25.7 million (61%), \$15.3 million (49%) and \$11.1 million (54%) for the three fiscal years ended March 31, 2002, 2001 and 2000 respectively.

BioMerieux. We have an agreement with BioMerieux (formerly Organon Teknika B.V.) for development and worldwide commercialization of ORIGIN-based nucleic acid probe systems to the clinical diagnostic and life science markets. BioMerieux specializes in hospital and blood bank products and has combined its proprietary nucleic acid sequence based amplification technology with ORIGIN technology and markets the NucliSens line of diagnostic virology products together with test kits for the detection of HIV-1 RNA and CMV (cytomegalovirus). We have received \$20 million under our agreement with BioMerieux and currently receive royalties on product sales.

Eisai Co., Ltd. We have a collaboration with Eisai Co., Ltd., a leading Japanese pharmaceutical company, to market an ORIGIN-based diagnostic system for the clinical diagnostic market in Japan. Eisai introduced its first ORIGIN-based product under the trade name Picolumi during 1997, and we receive royalties on product sales. Eisai is currently marketing the Picolumi product with assays focused primarily in the area of cancer diagnosis.

Meso Scale Diagnostics, LLC. During August 2001, we entered into agreements with Meso Scale Technologies, LLC. ("MST") continuing Meso Scale Diagnostics, LLC. ("MSD"), a joint venture formed solely by MST and us in 1995. MSD

was formed for the development and commercialization of products utilizing a proprietary combination of MST's multi-array technology together with ORIGIN and other technologies owned by us. MST is a company established and wholly-owned by the son of IGEN's Chief Executive Officer. Under most circumstances, significant MSD governance matters require the approval of both us and MST.

Under the amended agreements that were negotiated by an independent committee of our Board of Directors, we hold a 31% voting equity interest in MSD, and are entitled to a preferred return on \$36.4 million of the funds previously invested in MSD through March 31, 2002 and on additional funds we invest thereafter. This preferred return would be payable out of a portion of both future profits and certain third-party financings, before any payments are made to other equity holders. MST owns the remaining 69% of the voting equity interest in MSD. We agreed, subject to certain conditions, to fund the joint venture through November 2003. During the 2002 calendar year, we agreed to fund MSD \$21.5 million, subject to a permitted variance of fifteen percent. As of March 31, 2002, the Company has satisfied \$5.3 million of this funding commitment. The 2003 calendar year funding commitment would be based on an annual budget to be approved by a committee of our Board of Directors.

The funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. If the 2003 budget is not approved by our Board of Directors, we would be required to provide transitional funding for an additional six months, estimated at \$11.0 million, and under certain conditions, MSD and MST have the right to terminate the joint venture prior to November 2003 under certain circumstances, including a change in control of the Company, as defined. Upon termination, expiration or non-renewal of the joint venture agreement, MSD and MST have the right to purchase our interest in MSD at fair market value less certain discounts.

MSD has developed two instrument systems, the Sector PR and the Sector HTS, along with a variety of consumables which were initially introduced to the life science market in September 2001. The first MSD beta test site was established in March 2002.

For the years ended March 31, 2002, 2001 and 2000, we made total contributions to MSD of \$19.6 million, \$8.3 million and \$4.5 million, respectively. See ITEM 7 "Management's Discussions and Analysis of Financial Condition and Results of Operations," and ITEM 13 "Certain Relationships and Related Transactions."

Patents and Other Proprietary Rights

We pursue a policy of seeking patent protection to preserve our proprietary technology and our right to capitalize on the results of our research and development activities and, to the extent it may be necessary or advisable, to exclude others from appropriating our proprietary technology. We also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We prosecute and defend our intellectual property, including our patents, trade secrets and know-how. We regularly search for third-party patents in our fields of endeavor, both to shape our own patent strategy as effectively as possible and to identify licensing opportunities.

As of March 31, 2002, we owned 63 issued U.S. patents and had 23 pending U.S. patent applications in the diagnostics field. As of that date, we owned 130 additional issued patents outside of the United States and had 68 pending patent applications. These patents and patent applications are important to our business and cover various aspects of our ORIGIN technology and products, as well as the methods for their production and use. The pending patent applications may not be granted and others may challenge our existing patents. Our business could be harmed if we lose the patent protection we currently enjoy or if our pending patents are not issued.

Our patents will not begin to expire until 2005; core ORIGIN patents will extend through 2015. We continue to protect our technology with new patent filings, which could further extend our patent coverage.

Government Regulation

Our research and development, manufacturing and marketing activities of both existing and future products are subject to regulation by numerous governmental authorities in the United States and other countries. In the United States, clinical diagnostic devices are subject to rigorous FDA regulation. The Federal Food, Drug and Cosmetic Act and the Public Health Service Act govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our clinical products.

In addition to FDA regulations, we are subject to other federal and state regulations such as occupational safety and health regulations and environmental regulations. Product development and approval within this regulatory framework may take a number of years and involves the expenditure of substantial resources.

In addition, this regulatory framework may change or additional regulation may arise at any stage of our product development, which may affect approval of or delay an application or require additional expenditures by us.

Our regulatory strategy is to pursue development and marketing approval of products worldwide, either independently or through corporate collaborators. We intend to seek input from the regulatory authorities at each stage of the clinical process to facilitate appropriate and timely clinical development. The clinical development of certain products may be the responsibility of our collaborators.

Clinical Diagnostic Systems

The manufacture, distribution and sale in the United States of our products for clinical diagnostic purposes will require prior authorization by the FDA. The FDA and similar agencies in foreign countries have promulgated substantial regulations that apply to the testing, marketing, export and manufacturing of diagnostic products. To obtain FDA approval of a new product for diagnostic purposes, we or our collaborators will in most cases be required to submit proof of the safety and efficacy of the product, or its "substantial equivalence" to previously marketed products. Such proof typically entails clinical and laboratory tests. The testing, preparation of necessary applications and processing of those applications by the FDA is expensive and time consuming.

Significant difficulties or costs may be encountered in order to obtain FDA approvals and that could delay or preclude us from marketing products for diagnostic purposes. Furthermore the FDA may request additional data following the original submission. Delays imposed by the governmental approval process may materially reduce the period during which we or our collaborators will have the exclusive right to exploit our products or technologies.

Our clinical diagnostic products are regulated as medical devices. The Roche Elecsys clinical diagnostic products have received FDA approval. Prior to entering commercial distribution, all medical devices must undergo FDA review under one of two basic review procedures depending on the type of assay: a Section 510(k) pre-market notification ("510(k)") or a pre-market approval application ("PMA"). 510(k) notification is generally a relatively simple filing submitted to demonstrate that the device in question is "substantially equivalent" to another legally marketed device. Approval under this procedure may be granted within 90 days if the product qualifies, but generally takes longer, and may require clinical testing.

When the product does not qualify for approval under the 510(k) procedure, the manufacturer must file a PMA to show that the product is safe and efficacious, based on extensive clinical testing among several diverse testing sites and population groups, and shows acceptable sensitivity and specificity. This procedure requires much more extensive pre-filing testing than does the 510(k) procedure and involves a significantly longer FDA review after the date of filing. In responding to a PMA, the FDA may grant marketing approval, may request additional information, may set restrictive limits on claims for use or may deny the application altogether.

After product approvals have been received, they may still be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. The FDA may require surveillance programs to monitor the effect of products that have been commercialized, and has the power to prevent or limit further marketing of the products based on the results of these post-marketing programs.

In addition to obtaining FDA approval for each product, under the PMA guidelines, the Company must seek FDA approval of the manufacturing facilities and procedures. The FDA will also inspect diagnostic companies on a routine basis for regulatory compliance with its GMP.

Our products for the physician's office market will be affected by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), which is intended to insure the quality and reliability of medical testing and may have the effect of discouraging, or increasing the cost of, testing in physicians' offices.

The regulations establish requirements for laboratories in the area of administration, participation in proficiency testing, patient test management, quality control, personnel, quality assurance and inspection. Under these regulations, the specific requirements that a laboratory must meet depend upon the complexity of the tests performed by the laboratory.

Laboratory tests are categorized as either waived tests, tests of moderate complexity or tests of high complexity. Laboratories that perform either moderate or high complexity tests must meet standards in all areas, with the major difference in requirements between moderate and high complexity testing concerning quality control and personnel standards. Quality control standards for moderate complexity testing are being implemented in stages. Personnel standards for high complexity testing are more rigorous than those for moderate complexity testing. In general, personnel conducting high complexity testing will need more education

and experience than those doing moderate complexity testing. Under the CLIA regulations, all laboratories performing moderately complex or highly complex tests will be required to obtain either a registration certificate or certificate of accreditation from the Healthcare Financing Administration ("HCFA").

Because the regulations' interpretation is uncertain, it is possible that certain of our products may be categorized as tests of high complexity, in which case penetration of the point-of-care market would be reduced since not all laboratories would meet the standards required to conduct such tests. We understand that laboratories, including physician office laboratories, will be evaluating the requirements of CLIA in determining whether to perform certain types of moderate and high complexity diagnostic tests.

Although we believe that we will be able to comply with all applicable regulations regarding the manufacture and sale of diagnostic devices, such regulations are always subject to change and depend heavily on administrative interpretations. Future changes in regulations or interpretations made by the U.S. Department of Health and Human Services, FDA, HCFA or other regulatory bodies, with possible retroactive effect, may adversely affect us.

In addition to the foregoing, we are subject to numerous federal, state and local laws and regulations relating to such matters as safe working conditions, laboratory and manufacturing practices, environmental, fire hazard control, and disposal of hazardous or potentially hazardous substances. To date, compliance with these laws and regulations has not had a material effect on our financial results, capital requirements or competitive position, and we have no plans for material capital expenditures relating to such matters. However, we may be required to incur significant costs to comply with such laws and regulations in the future, and such laws or regulations may have a material adverse effect upon our ability to do business.

Sales of the Company's products outside the United States are also subject to extensive regulatory requirements, which vary widely from country to country. The time required to obtain such approval may be longer or shorter than that required for FDA approval.

Research Products

Our products that are being sold for research use only, including the M-SERIES System, must be properly labeled as such, as required by the FDA, but do not generally require

FDA approval prior to marketing. The FDA has begun to impose new distribution requirements and procedures on companies selling research-only products, such as the requirement that the seller receive specified certifications from its customers as to the customers' intended use of the product. We expect that the FDA will develop additional restrictions of this nature that may adversely affect us.

Environmental Regulation

Due to the nature of our current and proposed research, development and manufacturing processes, we are subject to stringent federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials and wastes. Although we believe that we have complied with these laws and regulations in all material respects and have not been required to take any action to correct any noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future.

Reimbursement

Third-party payers, such as governmental programs and private insurance plans, can indirectly affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement they will provide for diagnostic testing services. In recent years, healthcare costs have risen substantially, and third-party payers have come under increasing pressure to reduce such costs.

In this regard, the federal government, in an effort to reduce healthcare costs, may take actions that may involve reductions in reimbursement rates. If the reimbursement amounts for diagnostic testing services are decreased in the future, it may decrease the amount which physicians, clinical laboratories and hospitals are able to charge patients for such services and consequently the price we and our collaborators can charge for our products.

Competition

Competition varies in the three markets in which we operate. In the life science market, competition is fragmented. To be competitive, a company must be able to address the needs of pharmaceutical and biotechnology companies, which are facing pressure to increase productivity while decreasing drug discovery costs and timelines. These drug discovery companies favor detection systems that combine automation and enhanced sensitivity with integrated equipment and consumables.

Because our *ORIGEN* system encompasses all of these elements, we believe it offers significant advantages over competing systems. In addition, we, unlike some of our competitors, offer our customers assay development services, which we believe enhance the speed and robustness of their screening operations.

The clinical testing market is dominated by a few large multi-national companies, including Abbott Laboratories, Roche, Bayer and Johnson & Johnson. We participate in this market through our license arrangements with Roche, the world's largest provider of diagnostics products, BioMerieux and Eisai.

The industrial testing market is highly fragmented. While existing testing methods are relatively inexpensive, these technologies are time consuming and produce non-specific test results that are often unreliable.

As in the life science market, we are developing a portfolio of tests that would offer enhanced speed, reliability and specificity in detecting pathogens and other microbial contaminants in food, water and other industrial samples being tested. We believe this will allow us to position *ORIGEN* competitively as the detection method of choice for the industrial testing market.

Our competition will be determined in part by the potential applications for which our products are developed and ultimately approved by regulatory authorities. For certain of our future products, an important factor in competition may be the timing of market introduction of our own or competing products. Accordingly, the relative speed with which we or our corporate collaborators can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors.

We expect that competition with products approved for sale will be based, among other things, on product efficacy, safety, reliability, availability, price and patent protection.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. These companies may develop and introduce products and processes competitive with or superior to ours.

Our competitive position also depends upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or

processes and secure sufficient capital resources for the often substantial period between technological conception and commercial sales.

We do not hold a leading competitive position in the three principal markets in which we compete.

Manufacturing

Our current commercial manufacturing operations consist of the manufacture of the M-SERIES System and related reagents, PATHIGEN products and cell culture research biologicals. We operate a qualified GMP and ISO 9001 facility. We use a variety of suppliers and believe that we do not depend on any supplier that cannot be replaced in the ordinary course of business.

Any changes in source of supply may require additional engineering or technical development, with costs and delays that could be significant, in order to ensure consistent and acceptable performance of the products.

We have not yet introduced clinical diagnostic products that are manufactured by us. Initial clinical diagnostic products, based on our ORIGIN technology, are being manufactured by corporate collaborators. We are presently evaluating plans for future manufacturing of clinical diagnostic products that include direct or third party manufacturing.

Sales and Marketing

We market the M-SERIES System and the ORIGIN Detection System, together with related reagents and services, directly to the life science research market. In conjunction with the U.S. and European launch of the M-SERIES System, we have expanded our direct sales force, including the addition of application specialists and in-house technical service personnel. We also utilize distributors in Japan and Scandinavia. The ORIGIN cell culture products are sold directly and through distributors. Substantial sales and marketing of products based on our ORIGIN technology is conducted by corporate collaborators. See "Collaborations."

Human Resources

As of May 31, 2002, IGEN employed 370 individuals full-time, of whom 277 were engaged in research, product development, manufacturing and operations support, 55 in marketing, sales and applications support and 38 in general administration. Of our employees, 64 have Ph.D. degrees. A significant

number of our management and professional employees have had prior experience with pharmaceutical, biotechnology, diagnostic or medical products, computer software or electronics companies. None of our employees are covered by collective bargaining agreements, and management considers relations with its employees to be good.

The ability to maintain our competitive position will depend, in part, upon our continued ability to attract and retain qualified scientific, technical and managerial personnel. Competition for such personnel is intense.

Geographic Segments

Information on domestic and foreign product sales is incorporated herein by reference to ITEM 8—Consolidated Financial Statements—Notes to Consolidated Financial Statements—Note 11.

Executive Officers of the Company

The names and ages of all executive officers at May 31, 2002 and their respective positions and offices with us are set forth below. Each officer serves without a set term.

Name	Age	Position
Samuel J. Wohlstadter	60	Chairman, Chief Executive Officer and Director
Richard J. Massey, Ph.D.	55	President, Chief Operating Officer and Director
George V. Migausky	47	Vice President, Chief Financial Officer and Secretary

SAMUEL J. WOHLSTADTER is a founder of IGEN and has been our Chairman of the Board and Chief Executive Officer since 1982. Mr. Wohlstadter has been a venture capitalist for more than 25 years and has experience in founding, supporting and managing high technology companies, including Amgen Inc., a biotechnology company, and Applied Biosystems, Inc., a medical and biological research products company. Mr. Wohlstadter is also Chief Executive Officer of Hyperion Catalysis International, an advanced materials company, which he founded in 1981; of Pro-Neuron, Inc., a drug discovery company, which he founded in 1985; of Proteinix Corporation, a development stage company organized to conduct research in intracellular metabolic processes, which he founded in 1988; and of Pro-Virus, Inc., a drug discovery company, which commenced operations in 1984.

RICHARD J. MASSEY, Ph.D. is one of our founders and has been President and Chief Operating Officer since February 1992 and a director since 1990. He served as Senior Vice President from 1985 to 1992. From 1981 until he joined us in 1983, Dr. Massey was a faculty member in the Microbiology and Immunology Department at Rush Medical Center in Chicago. Prior to that, he was Senior Research Scientist at the Fredrick Cancer Center/National Cancer Institute.

GEORGE V. MIGAUSKY has been our Chief Financial Officer since 1985, assuming that position on a full-time basis in 1992. Between 1985 and 1992, in addition to serving as our Chief Financial Officer on a part-time basis, Mr. Migausky also served as financial advisor to several other privately held companies. Prior to joining us in 1985, he spent nine years in financial management and public accounting positions, most recently as a Manager with the High Technology Group of Deloitte & Touche.

Other Key Management

In addition to our executive officers and directors, we have the following managers directing key functions:

Name	Age	Position
Daniel Abdun-Nabi	47	General Counsel
Gerald Andros	40	Director of Sales
David Boudreau	45	Director of Operations
R. Don Elsey	48	Director of Finance and Administration
Stephen Kondor	47	General Manager—Clinical Diagnostics
Robert Proulx	45	General Manager—Life Science Business

DANIEL ABDUN-NABI joined us in September 1999 as General Counsel. He is responsible for all areas of corporate law, including advising us about our domestic and international legal matters, and he provides guidance in developing legal and business strategies and negotiating financial transactions. From 1990 to September 1999, Mr. Abdun-Nabi was Senior Vice President—Legal Affairs & General Counsel for North American Vaccine, Inc., where he oversaw domestic and international legal issues for that pharmaceutical company and its operating subsidiaries. Prior to that, Mr. Abdun-Nabi spent several years in private practice in Washington, D.C. and served for three years as an attorney with the Division of Corporation Finance at the SEC.

GERALD ANDROS has been our Director of Sales for Life Science since 1994. He is responsible for sales of ORIGEN products both in the United States and internationally. Prior to joining us, Mr. Andros spent six years working in sales management, marketing and sales training for Abbott Laboratories, where he focused on sales of immunoassay, chemistry and hematology product lines.

DAVID BOUDREAU joined us in August 1999 as Director of Operations. He is responsible for manufacturing, logistics and inventory management. From 1995 to August 1999, Mr. Boudreau served as Director of Manufacturing Operations at i-Stat, a medical diagnostics company, where he handled operational planning and supply chain management for the United States and Canada. Prior to that he held the position of Manufacturing Manager at Analog Devices Inc. and worked as a process engineer at Chevron USA.

R. DON ELSEY joined us in May 2000 as Director of Finance and Administration. He is responsible for the accounting, treasury, risk management, and human resources functions for us. From April 1998 to February 2000, Mr. Elsey served as Director of Finance at PE Biosystems. From 1980 to April 1998, Mr. Elsey held a variety of financial management positions with International Business Machines, Inc.

STEPHEN KONDOR joined us in September 2001 as General Manager, Clinical Diagnostics. He has 22 years experience in the medical device, clinical diagnostic, and life science markets, including 14 years for Abbott Labs Diagnostic Products Division where during his tenure, he held various sales, marketing, and business general management positions most recently as Worldwide Commercial Director for the Hematology Business Unit. Mr. Kondor was Senior Vice President at Avocet Medical from January 2000 until joining us in September 2001, where he was responsible for marketing products to the point of care clinical diagnostic community. From 1996 to 2000, he was Executive Vice President World Wide Marketing & Sales at Biometric Imaging, Inc.

ROBERT PROULX joined us in March 2000 as General Manager of the Life Sciences Business. Mr. Proulx has primary responsibility for managing sales, marketing and product development efforts for our life science research business. From 1989 to February 2000 Mr. Proulx held various positions at Packard Instrument Company, Inc., which specializes in instrumentation and reagents for the life science research market. Immediately prior to leaving Packard, Mr. Proulx served as Vice President, Marketing.

Risk Factors

IF THE COMPANIES THAT LICENSE TECHNOLOGY FROM US DO NOT EFFECTIVELY DEVELOP AND MARKET PRODUCTS BASED ON THAT TECHNOLOGY, OUR REVENUE WOULD BE ADVERSELY AFFECTED.

The success of our business depends, in large part, on how effectively the companies to which we have licensed our technology develop and market that technology. If these companies do not effectively develop and market products based on this technology, our revenues would decrease.

We have licensed our technology to BioMerieux, Eisai Co., Ltd., and Roche Diagnostics GmbH for selected markets and uses. Our license agreements with each of these companies allow each company to develop products using our technology and to manufacture and sell those products in selected markets. In return for the right to use our technology, each of these companies must pay royalties to us based on revenues they receive from sales of products based on our technology. These royalties are a significant part of our overall revenue.

For example, they accounted for 64% of our revenue in fiscal year 2002. We have brought a lawsuit against Roche, one of our licensees, in part because we believe Roche has not properly calculated and paid royalties to us. See the risk factor immediately below for a more detailed description of this litigation and the risks it poses to us. Similar or other problems may arise with other companies to whom we license our technology.

WE ARE SUING THE LARGEST LICENSEE OF OUR TECHNOLOGY, AND THE OUTCOME OF THAT LITIGATION COULD MATERIALLY ADVERSELY AFFECT OUR REVENUES AND FINANCIAL CONDITION.

We have an ongoing lawsuit against Roche, which is the largest licensee of our technology in terms of royalty income accounting for over 90% of our royalty income in fiscal 2002. The lawsuit centers on a number of claims we assert against Roche in which we allege that they failed to comply with the terms of our license agreement with them. Roche filed a counterclaim against us in the lawsuit alleging, among other things, that we breached the Roche license agreement by permitting Eisai Co. Ltd., another of our licensees, to market some ORIGEN-based products in Japan.

The United States District Court issued a final order of judgment in our case against Roche that awarded us \$105 million in compensatory damages and \$400 million in punitive damages, confirmed our right to terminate the Roche license

agreement, directed and commanded Roche to grant to us for use in our retained fields a license to all improvements developed by Roche under the agreement, including Roche's Elecsys® diagnostics product line, and barred Roche from marketing, selling, placing or distributing outside of its licensed field any products, including its Elecsys diagnostics product line, that are based on our ORIGEN® technology. We have voluntarily agreed not to terminate the license agreement until an appellate court determines that we are entitled to do so; however, we have already notified Roche that the license agreement will terminate automatically once the judgment is affirmed by the Court of Appeals.

The final judgment issued in this case also found in our favor and against Roche on all of Roche's counterclaims, except for one in which we were ordered to pay \$500,000. Roche has filed a notice of appeal. During the appeal process, Roche is obligated to continue to comply with the terms of the license agreement.

The risks involved in the litigation include:

- The appellate court may modify or overturn some or all of the judgment favorable to us including the finding that Roche materially breached the license agreement, the scope and extent of the improvements awarded to us, the amount of compensatory and punitive damages, or the favorable findings relating to Roche's counterclaims against us.
- The appellate court could overturn some or all of the judgment and order a new trial on those issues. For example, if the court orders a new trial on whether or not Roche miscalculated and underpaid royalties, breached its duty of good faith and fair dealing, or engaged in unfair competition against us, the amount of damages awarded in a new trial could be lower than the amount already awarded to us.
- If the court orders a new trial on any of the issues, we might need to continue expending significant amounts of money and management time in pursuing our claims against Roche. This time and money will then be unavailable for use in the development of our business.
- If the appellate court upholds the judgment that Roche materially breached the license agreement, and the license agreement is terminated, our royalty revenues would suffer unless and until we were able to introduce new products and generate revenues on our own or find one or more comparable replacements for Roche.

- We may not be able to find a suitable replacement for Roche or successfully introduce new products on our own following termination of the license. Our ability to successfully commercialize new products, including products based on the improvements awarded to us in this litigation, is subject to numerous risks and uncertainties including risks relating to:
 - the need for governmental approvals;
 - our ability to compete effectively;
 - our ability to effectively manufacture and market new products;
 - our ability to attract and retain employees;
 - our need for additional financing;
 - our dependence on suppliers; and
 - the other risks applicable to our business as more completely described herein and in other filings with the SEC.

While an appeal is pending, Roche may divert its attention from selling the licensed products that generate royalties to us and focus its energies instead to find alternative products to develop and market.

While an appeal is pending, Roche may continue to market and sell other Roche products that compete with its *ORIGEN*-based products, thereby lowering the royalty revenues that we would have otherwise received if Roche had sold more *ORIGEN*-based products instead of its other competing products.

We also sued Hitachi Ltd. which manufactures diagnostic equipment based on *ORIGEN* technology for Roche. On June 13, 2002, we and Hitachi reached agreement that settled this lawsuit. In the past, Roche has attempted to sue us for interfering with its contract with Hitachi because we filed this lawsuit. That claim was twice dismissed by the court. Roche may, following this settlement agreement, try to bring this claim against us again.

FAILURE TO MEET OUR DEBT OBLIGATIONS COULD ADVERSELY AFFECT OUR RESULTS OF OPERATIONS AND FINANCIAL CONDITION; IN ADDITION, OUR DEBT SERVICE OBLIGATIONS COULD IMPAIR OUR OPERATING FLEXIBILITY.

We have a total debt balance at March 31, 2002 of \$53.2 million. There is a possibility that we may be unable to generate cash or arrange financing sufficient to pay the principal of,

interest on and other amounts due in respect of our indebtedness when due, or in the event any of our indebtedness is accelerated.

Termination of the license agreement with Roche would cause approximately \$23.1 million of our debt payment obligations as of March 31, 2002, under our 8.5% senior secured notes to accelerate. The note purchase agreement for the 8.5% senior secured notes also contains covenants that limit our ability to take specified actions, including incurring additional secured debt and amending our license agreement with Roche, which could affect our ability to resolve issues that are being litigated through an amendment to the existing license agreement with Roche. These restrictions may limit our operating flexibility, as well as our ability to raise additional capital.

In addition, our substantial leverage may require that we dedicate a substantial portion of our expected cash flow from operations to service our indebtedness, which would reduce the amount of our expected cash flow available for other purposes, including working capital and capital expenditures.

In January 2000, we sold \$35 million in aggregate principal amount of 5% subordinated convertible debentures due 2005. Unless and until holders of the debentures convert their debentures into Common Stock, we are required to make semi-annual interest payments of \$875,000 through 2005. If we are unable to meet our obligations under the subordinated convertible debentures, the debenture holders could require us to repay the principal amount of, and accrued interest on, the subordinated convertible debentures, and we may not have sufficient financial resources or be able to arrange sufficient financing to make those payments when required.

WE HAVE A HISTORY OF OPERATING LOSSES AND EXPECT TO INCUR FUTURE LOSSES.

We have experienced significant operating losses each year since our inception, and we expect those losses to continue. We also have an accumulated deficit. Our losses have resulted principally from costs incurred in research and development, litigation costs, selling costs and other general and administrative costs. We expect to incur additional operating losses as a result of increases in expenses for manufacturing, marketing and sales capabilities, litigation costs and expenses, research and product development, the transfer and commercialization of improvements from Roche, general and administrative costs and our share of losses in MSD.

We may not achieve profitability in the future. Our ability to become profitable in the future will depend on, among other things, our ability to:

- expand the commercialization of our existing products;
- upgrade and enhance the M-SERIES product capabilities;
- introduce new products into the market, including products for the markets currently served by Roche following termination of Roche's license with us;
- develop our marketing capabilities cost-effectively;
- develop sales and distribution capabilities cost-effectively; and
- establish successful collaborations with corporate partners to develop and commercialize products that incorporate our technologies.

OUR QUARTERLY OPERATING RESULTS MAY FLUCTUATE SIGNIFICANTLY, AND THESE FLUCTUATIONS MAY CAUSE OUR STOCK PRICE TO FALL.

Our quarterly operating results depend upon:

- the volume and timing of orders for M-SERIES or other products;
- the timing of instrument deliveries and installations;
- the success of M-SERIES upgrades and enhancements;
- variations in revenue recognized from royalties and other contract revenues;
- our mix of products sold;
- whether our instruments are sold to or placed with customers;
- the timing of our introduction of new products;
- our competitors' introduction of new products;
- variations in expenses we incur in connection with the operation of our business, including costs associated with the transfer of improvements from Roche to us, research and development costs including costs associated with developing and commercializing new products for the markets currently served by Roche, and sales and marketing costs, including costs for upgrading the M-SERIES products;
- our share of losses in MSD;
- our manufacturing capabilities; and
- the volume and timing of product returns and warranty claims.

These factors may cause our quarterly operating results to fluctuate significantly, which in turn, may cause our stock price to fall. In addition, because our revenues and operating results are volatile and difficult to predict, we believe that period-to-period comparisons of our results of operations are not a good indication of our future performance.

WE MAY NOT BE ABLE TO RAISE SUFFICIENT ADDITIONAL CAPITAL TO SUCCESSFULLY DEVELOP OUR BUSINESS.

We need substantial amounts of money to fund our operations. Our access to funds could be negatively impacted by many factors, including the results of pending litigation, the volatility of the price of Common Stock, continued losses from operations, acceleration of debt payment obligations resulting from termination of the license agreement with Roche and other factors.

We may need to raise substantial amounts of money to fund a variety of future activities integral to the development of our business, including the following:

- for research and development in order to successfully develop our technologies, including to develop new products for the clinical diagnostic markets that are currently being served by Roche;
- to obtain regulatory approval for some of our products;
- to file and prosecute patent applications in order to protect our technology;
- to respond to innovations that our competitors develop;
- to continue to aggressively pursue our ongoing litigation against Roche;
- to retain qualified employees, particularly in light of intense competition for qualified scientists and engineers;
- to make new arrangements to market our technology, including for the markets currently being served by Roche following the termination of our license agreement with Roche;
- to continue to fund investments in MSD;
- to manufacture products ourselves or through a third party; and
- to market different products to different markets, either through building our own sales and distribution capabilities or relying on a third party.

We may not have access to enough funds to successfully develop our business. We may try to raise necessary additional capital by issuing additional debt or equity securities. Holders of debt securities would have priority over our equity holders with respect to the proceeds from the sale of our assets in the event of liquidation of our business, and any debt financings we obtain may contain restrictive terms that limit our operating flexibility. If, on the other hand, we raise additional capital by selling more common or preferred stock, the holdings of existing stockholders would be diluted.

If we are unable to raise additional capital, we may have to scale back, or even eliminate, some programs. Alternatively, we may have to consider pursuing arrangements with other companies, which may not be on terms favorable to us

WE MAY NOT BE ABLE TO COMPETE EFFECTIVELY AGAINST MORE ESTABLISHED COMPANIES AND INSTITUTIONS, WHICH COULD ADVERSELY AFFECT OUR BUSINESS.

We are a relatively young company in a highly competitive industry. We compete against established companies and research and academic institutions, and we expect this competition to intensify. Many of these companies and institutions have one or more competitive advantages over us, including:

- more money to invest;
- greater expertise and resources in developing, manufacturing, marketing and selling products;
- a larger, more experienced workforce; and
- more experience in obtaining regulatory approval for clinical diagnostic products.

As a result, we may not be able to compete successfully against our current or future competitors. This could have a material adverse effect on our business, financial condition and revenue.

OUR PRODUCTS MAY BECOME OBSOLETE IF WE EXPERIENCE DIFFICULTIES OR DELAYS IN PRODUCT DEVELOPMENT.

The market for our products is characterized by rapidly changing technology, evolving industry standards, the need for updated and effective technology and new product introduction. Our future success will depend in part upon our ability to enhance existing products and to develop and introduce new or enhanced products. We may not be able

to avoid the obsolescence of our products due to rapid technological change and evolving industry standards. The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological and market trends as well as precise technological execution. We have and may continue to experience design, development, implementation and other difficulties that could delay or prevent our introduction of new or enhanced products or affect the performance of existing products. These difficulties and delays have caused, and may continue to cause, our expenses to increase and our product sales to fluctuate.

WE DEPEND ON HIGHLY TRAINED AND SKILLED EMPLOYEES AND MANAGEMENT, AND WE MAY NOT BE ABLE TO ATTRACT AND RETAIN SUFFICIENT PERSONNEL.

We need to hire additional staff and to retain existing staff, both of which are difficult in today's competitive marketplace. Because we are a technology company, we depend heavily on scientists and engineers to develop products and to build a successful business. Research and development efforts could suffer if we are not able to hire and retain enough qualified scientists and engineers. We compete with other technology companies and research and academic institutions for experienced scientists. Many of these companies and institutions have greater resources than we do and thus may be in a better position to attract desirable candidates.

In addition to scientists, we will also need to hire managers as the business grows. We will need managers who are able to address the need for regulatory, manufacturing and marketing capabilities. If we are not able to hire managers with these skills, or develop expertise in these areas, our business prospects could suffer.

WE DEPEND ON A LIMITED NUMBER OF SUPPLIERS FOR MATERIALS USED IN MANUFACTURING OUR PRODUCTS, AND ANY INTERRUPTION IN THE SUPPLY OF THOSE MATERIALS COULD HAMPER OUR ABILITY TO MANUFACTURE PRODUCTS AND MEET CUSTOMER ORDERS.

We depend on vendors to supply key materials that we use in our products. Some of these materials are available only from limited sources. In the event of a reduction in, interruption of, or degradation in the quality of the supply of any of our required materials, or an increase in the cost of obtaining those materials, we would be forced to locate an

alternative source of supply. If no alternative source were available or if an alternative source were not available on a timely basis or at a reasonable cost or otherwise on acceptable terms, our ability to manufacture one or more of our products would be delayed or halted. Any changes in sources of supply may require additional engineering or technical development in order to ensure consistent and acceptable performance of the products. If any of these events occur, product costs may increase, we might be unable to deliver products timely, we could lose sales as well as customers, and our business would be significantly harmed as a result.

WE MUST OBTAIN FDA APPROVAL TO MARKET OUR CLINICAL DIAGNOSTIC PRODUCTS, WHICH IS OFTEN COSTLY AND TIME CONSUMING, AND IF WE DO NOT OBTAIN THE NECESSARY APPROVAL OUR BUSINESS PROSPECTS WOULD SUFFER.

The FDA regulates many areas in which we conduct research and in which we develop, produce and market products. In particular, we must obtain FDA approval before we can market clinical diagnostic products such as those we are currently developing for the patient care market. The approval process is often costly and time consuming. We may not be successful in obtaining FDA approval for any of our clinical diagnostic products, which would materially adversely affect our future prospects.

In order to obtain FDA approval in the United States, we, or the companies with whom we work, will need to either obtain pre-market application approval or pre-market notification clearance from the FDA. In order to obtain pre-market notification clearance, we must submit data from clinical trials demonstrating that new clinical diagnostic systems are substantially equivalent to diagnostic systems that the FDA has already approved. If a product is subject to the substantial equivalence requirement, neither we, nor any of our licensees can sell that system for clinical use in the United States until the FDA determines that a new ORIGIN-based system is substantially equivalent to a previously approved system. Typically, the FDA review process takes 90 days, but the FDA's review could take longer. In addition, we may not be able to demonstrate substantial equivalence for future diagnostic systems.

If we do not successfully demonstrate substantial equivalence, or if we are required to obtain pre-market application approval as an initial matter, we will have to conduct extensive clinical testing of these products, which could take years to complete. Extensive testing could involve substantial additional costs

and might delay bringing clinical diagnostic products to market, weakening our competitive position. If we fail to obtain FDA approval for new products altogether, we will be unable to market our ORIGIN-based systems at all for clinical use in the United States.

WE ARE SUBJECT TO EXTENSIVE, ONGOING GOVERNMENT REGULATION, WHICH MAY INVOLVE SIGNIFICANT COSTS AND MAY RESTRICT OUR ABILITY TO CONDUCT BUSINESS.

We expect that we may need to spend a substantial amount of money to comply on an ongoing basis with the regulations of the FDA and other government agencies. Government agencies, such as the FDA and the Environmental Protection Agency, regulate manufacturers of diagnostic products and the manufacturing process itself.

The costs of complying with governmental regulations and any restrictions that government agencies might impose could have a significant impact on our business. As we increase our manufacturing, these costs will increase.

Whether we manufacture products ourselves or contract with another company to manufacture products based on our technology, the FDA will continually review and periodically inspect the manufacturing process. If the FDA were to discover a problem with our products, the manufacturing process or the manufacturing facility, the FDA could place restrictions on these products and on the manufacturer. For example, the FDA could require us to recall, or even totally withdraw, a product from the market or close a manufacturing facility. In addition to FDA regulations, the process of manufacturing products is subject to a variety of environmental and safety laws and regulations, including laws and regulations governing the use and disposal of hazardous materials. If we fail to comply with these laws or regulations, our business and financial condition could be materially adversely affected.

WE HAVE LIMITED MANUFACTURING AND MARKETING EXPERIENCE, WHICH PUTS US AT A COMPETITIVE DISADVANTAGE.

We lack experience in large-scale manufacturing, which could hamper our ability to manufacture existing products or new products that we develop. We have two options to address this issue. First, we could expand our internal ability to manufacture products. Second, we could contract with a third party to manufacture for us products based on our technology. If, however, we are unable to expand our own

manufacturing capability or find a suitable manufacturer on acceptable terms in a timely manner, we may be unable to meet demand for existing products and could be delayed in introducing new products to the market. Failure to meet demand for existing products or delays in introducing new products could put us at a competitive disadvantage and could harm our financial condition or our business prospects.

We will also need to develop greater selling, marketing and distribution capabilities. To market clinical diagnostic products directly to customers, and not through a licensee, we need to develop a substantial sales force with technical expertise. We also need to establish a distribution system to support the sales force. Alternatively, we could license or contract with another company to provide sales and distribution services for products, in much the same way as we have done with Roche, Eisai and BioMerieux. We may not be able to develop a sufficient sales and distribution force or find a suitable company to fill that role for us.

THE SUCCESS OF OUR BUSINESS DEPENDS ON PATENTS THAT WILL EXPIRE AND THAT MUST BE ACTIVELY PURSUED AND PROTECTED.

Our business depends heavily on patents that will expire over time and may be challenged or circumvented by competitors. Patents allow us to prevent others, for a time, from using our inventions to compete against us. Our business success or failure will depend, in part, on our ability to obtain and maintain adequate patent protection for the *ORIGEN* technology. Our current patents or future patents may not adequately protect our technology from being used by our competitors.

Because there is no consistent policy governing the scope of claims in medical patents, patent protection is uncertain. Companies may, for example, challenge and invalidate patents or circumvent valid claims in patents, all of which could make it necessary for us to defend our patents in litigation. Litigation over patents poses the following risks to our business:

- Litigation costs can be extremely high, which could drain our financial resources.
- Litigation over our patents could discourage other companies from working with us to develop and market new products based on technology covered by these disputed patents.
- If we lose some patent protection as a result of litigation, our competitive advantage could be eroded.

OUR BUSINESS WOULD BE HARMED IF WE VIOLATE THE PATENT RIGHTS OF OTHERS.

Our business success or failure will also depend, in part, on the patent rights of others. We license technology from other companies and academic institutions. Because access to this technology is necessary to our business, we must be certain that we comply with these license agreements. Our business could be harmed if we breached any of these license agreements and lost the rights to use this patented technology or if we were unable to renew existing licenses on acceptable terms or get additional licenses that we may need on acceptable terms.

We must also make sure that we do not infringe the patent rights of others. If we were to infringe others' patent rights we could be exposed to the following risks:

- We could be required to alter, or abandon, our products or processes.
- We could be required to obtain a license from the patent holder.
- We could lose customers that are reluctant to continue using our products or doing business with us.
- We could be forced to abandon development work that we had begun with respect to these products.
- We could be required to pay damages that could be substantial.

If we infringe others' patent rights, our business could be damaged if we were unable to make necessary alterations or obtain a necessary license on acceptable terms.

In addition, we may need to litigate the scope and validity of patents held by others and such litigation could be a substantial cost for us.

WE RELY ON TRADE SECRETS AND OTHER INFORMATION THAT CANNOT BE PROTECTED BY PATENTS, AND WE FACE RISKS THAT THIS INFORMATION WILL BE DISCLOSED TO OTHERS.

In addition to patents, we also rely in our business on trade secrets, know-how and other proprietary information. If this information were disclosed to competitors, our business would suffer. We seek to protect this information, in part, by entering into confidentiality agreements with licensees, employees and consultants, which prohibit these parties from disclosing our confidential information. These agreements

may not provide adequate protection for our trade secrets, know-how and other proprietary information or ensure that the information we share with others during the course of our business will remain confidential. We may not have sufficient legal remedies under the agreements or otherwise to correct or compensate for unauthorized disclosures or sufficient resources to seek redress.

RESTRICTIONS ON HEALTH CARE COSTS AND HEALTH CARE AND INSURANCE FINANCING PRACTICES COULD LIMIT DEMAND FOR OUR PRODUCTS.

In the United States and elsewhere, demand for clinical diagnostic testing is dependent, in part, on consumers' ability to be reimbursed for the cost of the tests by third-party payers, such as government agencies, health maintenance organizations and private insurers. Medicaid and other third-party payers are increasingly challenging the prices charged for medical services, including clinical diagnostic tests. They are also attempting to contain costs by limiting their coverage of, and the amount they will reimburse for, clinical diagnostic tests and other health care products.

Without adequate coverage and reimbursement, consumer demand for clinical diagnostic tests may decrease. Decreased demand would likely cause sales of our clinical diagnostic products, and sales by our licensees, to fall since fewer tests would be performed or prices would be lowered, or both. Reduced sales or royalty income would hurt our business and our business prospects.

In many foreign markets, governments directly set the prices that clinical diagnostic companies may charge for their products and services. In the United States, a number of legislative and regulatory proposals aimed at changing the health care system have been proposed in recent years. Foreign and domestic legislative and regulatory initiatives that limit health care coverage may have a materially adverse effect on our business and our business prospects.

WE ARE EXPOSED TO PRODUCT LIABILITY RISKS THAT, IF NOT ADEQUATELY COVERED BY INSURANCE, MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR FINANCIAL CONDITION.

We may not be able to adequately insure against risk of product liability. As we begin marketing products, we may face product liability for claims and lawsuits brought by customers. Damages awarded in product liability cases can be very large.

While we have product liability insurance, this coverage is limited. We may not have adequate product liability insurance to cover us against our potential liabilities or be able to maintain current levels of product liability insurance on acceptable terms, if at all. Claims or losses in excess of our current or future product liability insurance coverage could have a material adverse effect on our financial condition.

MEMBERS OF OUR MANAGEMENT TEAM EXERCISE SIGNIFICANT CONTROL OVER IGEN AND MAY BE ABLE TO CONTROL THE OUTCOME OF PROPOSED CORPORATE ACTIONS SUPPORTED OR OPPOSED BY OTHER IGEN STOCKHOLDERS.

Our officers and directors in aggregate, own or have the right to purchase, approximately 28% of Common Stock and our Chief Executive Officer owns approximately 21% of the Common Stock at June 17, 2002 of directors and may be able to control the outcome of proposed corporate actions supported or opposed by other IGEN stockholders.

FAILURE TO MANAGE OUR GROWTH COULD ADVERSELY AFFECT OUR BUSINESS.

We have grown rapidly and expect to continue to grow by hiring new employees in all areas of our operations, increasing our presence in existing markets and introducing new products we develop into new potential high-growth markets. Our growth has placed, and continues to place, a strain on our management and our operating and financial systems.

As we grow, our personnel, systems, manufacturing capabilities and resources, procedures and controls may be inadequate to support future operations. In order to accommodate the increased operations for sales and marketing, research and development, facilities and administration, we will need to hire, train and retain the appropriate personnel. We may also need to improve our financial and management controls, reporting systems and operating systems. We may encounter difficulties in developing and implementing other new systems.

In response to our growth, we have recently implemented a new enterprise resource planning system in order to automate all of our accounting, manufacturing, sales and purchasing. If the enterprise resource planning system fails to operate as we expect or experiences delays or interruptions, our operations, as well as our ability to manage our increased growth, could be materially adversely affected.

PROVISIONS OF OUR GOVERNING DOCUMENTS MAY DETER OTHERS FROM ATTEMPTING TO ACQUIRE US.

Our governing documents contain provisions designed to prevent hostile takeovers, which may limit the ability of stockholders to sell their stock at a premium in a takeover. According to our governing documents, stockholders can only act at annual meetings or at special meetings of stockholders. Stockholders are not allowed to act by written consent. In addition, stockholders are not allowed to call for a special meeting. Only our board of directors, the chairman of the board or the president may call a special meeting. These provisions may make it difficult for stockholders to force us to hold special meetings. These provisions may also limit the ability of stockholders to consider transactions that they may want to approve, such as a hostile takeover of us.

Our governing documents also contain other provisions that could make it more difficult for a change in control to be effected. Our board of directors can issue preferred stock and can determine the rights of those preferred stockholders without the approval of holders of Common Stock. For example, our board of directors could give preferred stockholders one or more votes on issues on which holders of Common Stock vote. This could have the effect of diluting the voting rights of holders of Common Stock, which might further discourage other companies from trying to acquire us.

In addition, our certificate of incorporation contains provisions dividing our board of directors into three classes. Each class serves until the third succeeding annual meeting, and one class is elected at each annual meeting of stockholders.

As a result, even if our stockholders might prefer to effect a change sooner, it could take at least two annual meetings of stockholders to change a majority of the members of the board of directors.

Furthermore, our certificate of incorporation authorizes, and we have adopted, a preferred share purchase rights plan, commonly referred to as a "poison pill." Under the rights plan, we made a dividend distribution to the stockholders of record on November 6, 1996 of one right to purchase from us one one-hundredth of a share of our preferred stock for each outstanding share of our Common Stock. The terms of the rights and the circumstances under which they may be exercised are contained in a rights agreement, which has been filed with the SEC.

These terms have been designed to deter hostile takeovers of us, even though our stockholders might favor a takeover, especially if it were to afford them an opportunity to sell their stock at a price above the prevailing market rate.

OUR STOCK PRICE IS VOLATILE AND COULD DROP PRECIPITOUSLY AND UNEXPECTEDLY.

Our Common Stock currently trades on The Nasdaq National Market. The prices of publicly traded stock often fluctuate. The price of our stock may rise or fall dramatically, even though our business performance has not changed. In the past, the stock price of technology companies has been especially volatile. We expect that this will continue to be the case.

In addition to these fluctuations, an investment in our stock could be affected by a wide variety of factors that relate to our business and industry, many of which are outside of our control. For example, the value of our Common Stock could be affected by:

- new product introductions;
- innovations by competitors;
- our competitors' announcements of their financial results;
- the failure of our operating results to meet or exceed the expectations of investors and analysts;
- changes in financial estimates and recommendations by security analysts;
- general economic conditions;
- disputes over patents or other proprietary rights;
- new or existing litigation, including our litigation with Roche;
- publicity;
- regulations;
- market conditions; and
- fluctuations in our performance and the performances of our licensees.

On May 22, 2002, we notified holders of the outstanding Series B shares that we plan to redeem those shares on July 9, 2002 for their liquidation value. We expect that holders will elect to convert their Series B shares into our common stock prior to that date, which could lead to volatility in our stock price.

WE DO NOT PLAN TO PAY ANY CASH DIVIDENDS ON OUR COMMON STOCK.

We have never paid cash dividends on our Common Stock and we have no plans to pay cash dividends in the foreseeable future.

THE VALUE OF THE COMMON STOCK MAY BE DILUTED IN THE FUTURE.

Our officers, directors, employees and consultants have options to purchase a significant aggregate amount of our Common Stock. If they exercise their options and purchase Common Stock, our Common Stock will be diluted. In addition, we currently have preferred stockholders and convertible debenture holders who have the right to convert their preferred shares and debentures, as the case may be, to Common Stock. Our Common Stock would be diluted if these preferred stockholders or convertible debenture holders decide to convert their securities in the future. Moreover, our Common Stock could be further diluted if we issue additional Common Stock or securities convertible into Common Stock in the future, which we may need to do to raise funds for our business.

Sales of additional shares of our Common Stock or the conversion of securities into our Common Stock could cause the market price of our Common Stock to decrease.

ITEM 2. PROPERTIES

Our principal administrative, marketing, manufacturing and research and development facilities consist of approximately 116,000 square feet located in four buildings in Gaithersburg, Maryland. Our leases expire at various times from 2005 through 2010. We have an additional 23,000 square feet of leased research and development and sales facilities in Vienna, Virginia; San Diego, California; and Oxford, England. We believe that current facilities should be adequate for anticipated expansion needs.

ITEM 3. LEGAL PROCEEDINGS Roche Diagnostics (Roche)

In 1997, the Company filed a lawsuit against Roche Diagnostics GmbH (formerly Boehringer Mannheim GmbH) in the Southern Division of the United States District Court for the District of Maryland. The lawsuit arises out of a 1992 License and Technology Development Agreement (the "Agreement"), under which the Company licensed to Roche certain rights to develop and commercialize diagnostic products based on the Company's ORIGEN technology. In its lawsuit, the Company alleged that Roche failed to perform

certain material obligations under the Agreement and engaged in unfair competition against the Company.

The jury trial in this litigation was completed in January 2002, and in February 2002, the Court issued a final order of judgment that awarded the Company \$105 million in compensatory damages and \$400 million in punitive damages, confirmed the Company's right to terminate the Agreement, and directed and commanded Roche to grant to the Company for use in its retained fields a license to certain improvements developed by Roche under the Agreement.

Roche was also ordered, at its sole cost and expense, to deliver such improvements to the Company and to provide all other information and materials required or necessary to enable the Company to commercialize these improvements. Improvements, as defined in the judgment, include Roche's Elecsys® 1010, 2010 and E170 lines of clinical diagnostic immunoassay analyzers, the tests developed for use on those systems, and Roche's nucleic acid amplification technology called PCR. The jury further concluded that Roche violated its duty to the Company of good faith and fair dealing, engaged in unfair competition against the Company, and materially breached the license agreement.

The judgment bars Roche from marketing, selling, placing or distributing outside of its licensed field any products, including its Elecsys diagnostics product line, that are based on the Company's ORIGEN® technology. While the Company has voluntarily agreed not to terminate the Agreement until an appellate court determines that it is entitled to do so, the Company has notified Roche that the Agreement will terminate automatically once the Company's right is affirmed by the appellate court. Upon termination, Roche will be prohibited from commercializing all ORIGEN-based products in all fields. At that time, the Company will be free to operate, either independently or with new partners, in all fields, including those currently licensed to Roche.

Roche filed counterclaims against the Company alleging, among other things, that IGEN breached the Agreement by permitting Eisai Co., Ltd., another of the Company's licensees, to market certain ORIGEN-based products in Japan. The final judgment issued in the litigation found in the Company's favor and against Roche on all of Roche's counterclaims, except for one in which we were ordered to pay \$500,000.

Roche has filed a notice of appeal with the U.S. Court of Appeals for the Fourth Circuit. In connection with the filing of that appeal, Roche posted a \$600 million bond to support

its financial obligations to the Company under the judgment. During the appeal process, which the Company expects will be completed in 2003, Roche is obligated to continue to comply with the terms of the Agreement, including its obligation to continue to pay the Company royalties on Roche's sales of royalty-bearing products and to share and deliver improvements.

Roche's obligation to pay the \$505 million of monetary damages awarded to the Company is suspended until completion of the appeal process. The Company has also filed a notice of appeal on the judgment issued under the Roche counterclaim. Although the Company will vigorously oppose Roche's appeal, Roche may ultimately prevail in its attempt to modify or overturn the judgment issued in this litigation.

In 1998, a subsidiary of Ares-Serono ("Serono") filed a patent infringement claim against the Company, Roche and BioMerieux (formerly Organon Teknika) in the U.S. District Court, District of Delaware. The action claimed that a Serono patent was being infringed by the parties. Subsequently, F. Hoffman LaRoche, Ltd., a member of the Roche family of companies, acquired the patent from Serono and continued in Serono's place to assert the infringement claim against the Company and BioMerieux. A trial was held on this matter during February 2001. During November 2001, a settlement was reached between the Company and Roche under which Roche dismissed with prejudice all claims against the Company, paid the Company \$5.7 million as reimbursement for legal fees incurred in the litigation and granted the Company a fully paid-up, perpetual, worldwide, non-exclusive license (with the right to grant sublicenses) to the patent in suit.

Hitachi

In 1997, IGEN International K.K., a Japanese subsidiary of the Company, filed a lawsuit in Tokyo District Court against Hitachi Ltd. ("Hitachi"). The lawsuit sought to enjoin Hitachi from infringing a license registration held by IGEN K.K. and Eisai Co., Ltd., a company to which IGEN has licensed ORIGEN technology rights. The lawsuit requested injunctive relief preventing Hitachi from manufacturing, using or selling the Elecsys 2010, which incorporates the Company's patented ORIGEN technology, in Japan. On June 13, 2002, Hitachi and the Company reached an agreement to settle this litigation and the case has been dismissed.

Other Proceedings

In February 2001, Brown Simpson Strategic Growth Fund L.P., Brown Simpson Strategic Growth Fund, Ltd. and Brown Simpson Partners I (collectively "Brown Simpson")

initiated a shareholder derivative lawsuit for and on behalf of the shareholders of the Company in the Circuit Court for Montgomery County, Maryland against four of the Company's current directors, two former directors, three executive officers and the Company as a nominal defendant. In the complaint, Brown Simpson alleged breach of fiduciary duties by the named individual defendants in connection with transactions between the Company and other entities in which certain directors and officers are alleged to have an interest, including the Meso Scale Diagnostics, LLC. joint venture.

In March 2001, a second shareholder derivative lawsuit was filed by Laurence Paskowitz in the Circuit Court for Montgomery County, Maryland with allegations substantially the same as those set forth in the complaint filed by Brown Simpson. The complaint was later amended to add direct claims against the defendants and to seek class action certification for those direct claims.

Both lawsuits sought principally the following: that the defendants hold in trust and be required to account for and restore to the Company damages that IGEN has allegedly sustained by reason of the allegations and relief relating to board and management composition. The Paskowitz complaint also sought damages for a class of IGEN shareholders for the direct claims against the individual defendants. The complaints did not include any claims against the Company.

The Company and the individual defendants filed motions to dismiss or, in the alternative, for summary judgment in both lawsuits. On May 15, 2002, following hearings in December 2001 and March 2002, the court issued an opinion and order dismissing all claims asserted against all of the defendants. On June 19, 2002, an appeal was filed by one of the plaintiffs. The Company believes that the claims are without merit and it intends to vigorously oppose the appeal filed in this case.

The Company is involved, from time to time, in various other legal proceedings arising in the ordinary course of business. In the opinion of management, the Company does not believe that any legal proceedings described as Other Proceedings will have a material adverse impact on its financial position, results of operations or cash flows.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to a vote of security holders of the Company during the fourth quarter of the fiscal year covered by this report.

PART II

ITEM 5. MARKET FOR COMPANY'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS

The Company's Common Stock is quoted on The Nasdaq National Market under the symbol IGEN. As of June 17, 2002, there were approximately 8,300 holders of record of the Company's Common Stock. No cash dividends have been paid on the Common Stock to date, and the Company currently intends to retain any earnings for development of the Company's business.

The following table sets forth, for periods indicated, the range of high and low closing sales prices of the Common Stock as quoted on The Nasdaq National Market.

<u>Fiscal 2002</u>	<u>High</u>	<u>Low</u>
First Quarter	\$26.00	\$16.75
Second Quarter	\$32.72	\$23.55
Third Quarter	\$40.52	\$26.98
Fourth Quarter	\$44.23	\$35.84
<u>Fiscal 2001</u>		
First Quarter	\$23.50	\$12.88
Second Quarter	\$21.88	\$15.75
Third Quarter	\$24.88	\$10.25
Fourth Quarter	\$18.94	\$11.06

The following table sets forth, as of March 31, certain information with respect to compensation plans under which the Company's common stock is authorized for issuance.

Equity Compensation Plan Information

Plan Category	COLUMN A	COLUMN B	COLUMN C
	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	1,335,829	\$13.31	822,558
Equity compensation plans not approved by security holders	0	Not applicable	250,000
Total	<u>1,335,829</u>	<u>\$13.31</u>	<u>1,072,558</u>

Description of 2001 Broad Based Option Plan

The 2001 Broad Based Plan provides for the grant of options for up to 250,000 shares of the Company's common stock. As of March 31, 2002, no options have been granted under this plan. The purpose of the plan is to attract and retain the services of selected employees. The plan is administered by a committee of the Board of Directors, which has the authority to interpret, and grant options under, the plan. Options may only be granted to employees who are not officers or directors of the Company. The exercise price for options granted under the plan may not be less than fair market value of the Common Stock on the date of grant. Options will vest in accordance with a schedule determined by the committee and will have a term of up to ten years. The plan will terminate on July 24, 2010, although the Board may suspend or terminate the plan at any time.

The number of shares related to outstanding options will be subject to adjustment for stock dividends, splits and other similar events. If any outstanding option expires, or is terminated or canceled without being exercised, then the shares underlying the option will again be available for grant under the plan. In the event of a dissolution, liquidation, merger, or other corporate reorganization, any surviving corporation will be required to assume the outstanding options, substitute similar options, or allow the outstanding options to continue. If any surviving corporation fails to do so, then the outstanding options will become immediately exercisable and will expire if not exercised before the stated event.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below with respect to the Company's consolidated statements of operations for each of the years in the three-year period ended March 31, 2002 and with respect to the consolidated balance sheets at March 31, 2002 and 2001 are derived from, and are qualified by reference to, the consolidated financial statements that have been audited by Deloitte & Touche LLP, independent auditors, and are included elsewhere in this Form 10-K. The statement of operations data for each of the years in the two-year period ended March 31, 1999, and the balance sheet data at March 31, 2000, 1999 and 1998 are derived from audited financial statements not included in this Form 10-K.

The following selected financial data should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Form 10-K.

	2002	Fiscal Years Ended March 31,			1998
		2001	2000	1999	
<i>(in thousands, except per share data)</i>					
Statements of Operations Data:					
Revenues:					
Product sales	\$ 14,583	\$ 10,913	\$ 7,743	\$ 4,949	\$ 5,614
Royalty income	26,768	16,157	12,218	9,439	5,024
Contract fees	696	4,292	700	510	2,795
Total	<u>42,047</u>	<u>31,362</u>	<u>20,661</u>	<u>14,898</u>	<u>13,433</u>
Operating Costs and Expenses:					
Product costs	5,937	3,625	2,262	1,340	1,716
Research and development	27,203	28,497	18,665	14,271	11,615
Selling, general and administrative	24,164	16,849	13,989	10,676	10,897
Litigation costs	11,299	13,782	6,295	2,571	864
Total	<u>68,603</u>	<u>62,753</u>	<u>41,211</u>	<u>28,858</u>	<u>25,092</u>
Loss from operations	(26,556)	(31,391)	(20,550)	(13,960)	(11,659)
Other (expense) income, net	(5,023)	(4,867)	(11,855)	651	(171)
Equity in loss of affiliate	(10,947)	—	—	—	—
Loss before cumulative effect of accounting change	(42,526)	(36,258)	(32,405)	(13,309)	(11,830)
Cumulative effect of accounting change	—	(6,995)	—	—	—
Net loss	(42,526)	(43,253)	(32,405)	(13,309)	(11,830)
Preferred dividends	(1,402)	(2,052)	(2,137)	(1,980)	(541)
Net loss attributed to common stockholders	<u>\$(43,928)</u>	<u>\$(45,305)</u>	<u>\$(34,542)</u>	<u>\$(15,289)</u>	<u>\$(12,371)</u>
Basic and diluted net loss per common share	<u>\$ (2.20)</u>	<u>\$ (2.84)</u>	<u>\$ (2.24)</u>	<u>\$ (1.00)</u>	<u>\$ (0.82)</u>
Shares used in computing net loss per common share	<u>19,947</u>	<u>15,929</u>	<u>15,415</u>	<u>15,318</u>	<u>15,116</u>

	2002	2001	March 31, 2000	1999	1998
<i>(in thousands)</i>					
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 74,819	\$ 15,089	\$ 38,486	\$ 34,374	\$ 23,122
Working capital	73,416	9,096	38,537	32,327	17,590
Total assets	106,198	39,133	57,798	45,823	30,391
Long term obligations	51,397	56,821	59,605	32,704	146
Accumulated deficit	(200,023)	(157,497)	(114,244)	(81,839)	(68,530)
Stockholders' equity (deficit)	38,519	(36,373)	(11,808)	5,590	20,862

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We have devoted substantial resources to the research and development of our proprietary technologies, primarily the ORIGIN technology for the clinical diagnostic, life science and industrial markets. We currently derive a majority of our revenue from royalties received from licensees that develop and market certain ORIGIN-based systems. We also generate sales of our own products, particularly the M-SERIES System and related consumable reagents. We may selectively pursue additional strategic alliances, which could result in additional license fees or contract revenues. Since inception, we have incurred significant losses and, as of March 31, 2002, we had an accumulated deficit of \$200 million. We expect to continue to incur substantial research and development, manufacturing scale-up and general and administrative costs associated with our operations. As a result, we will need to generate higher revenue from present levels to achieve profitability.

Results of Operations

Years Ended March 31, 2002 and 2001

Revenues. Total revenues for the fiscal year ended March 31, 2002 increased by approximately \$10.6 million or 34% to \$42.0 million from \$31.4 million in fiscal 2001. The revenue growth for fiscal 2002 was due to increases in product sales and royalty income. Product sales were \$14.6 million in fiscal 2002, an increase of 34% over the prior year's product sales of \$10.9 million. This growth in product sales was led by the M-SERIES line of instrumentation and consumable life science products (\$3.2 million), as well as the revenue generated from the sale of clinical diagnostic assays to physician office laboratory (POL) customers in the United States, which increased by \$500,000. We began serving these POL customers in June 2000 when Roche transferred the customers in order to comply with a court ordered preliminary injunction. In February 2002, the Maryland federal court issued a final order of judgment against Roche which does not require Roche to renew existing POL contracts, some of which are scheduled to expire during fiscal 2003. Should POL customer contracts not be renewed, future POL product sales would experience a decline.

Royalty income was \$26.8 million in fiscal 2002, an increase of 66% over the prior year's royalty income of \$16.2 million. Royalties from Roche represent approximately \$25.7 million (96%) of the total royalty income for fiscal 2002 as compared to approximately \$15.3 million (94%) for fiscal 2001. These increases are attributable to higher Roche sales of its Elecsys and E170 product lines, which are based on IGEN's ORIGIN technology that was licensed to Roche under a 1992 license agreement, as well as certain modifications made by Roche to their methodology for computing royalties as a result of the litigation. While we are not satisfied that Roche is properly calculating and paying the required royalties, the recent changes in the way in which Roche calculates and pays its royalties to us is expected to have a continued positive impact on our royalty income in future periods. However, we have notified Roche that their license to sell ORIGIN-based products will be terminated once our right to do so is affirmed on appeal, in which case our royalty income from Roche would cease. See Item 3, "Legal Proceedings."

Contract revenue in the current fiscal year decreased to \$696,000 from \$4.3 million last year. The current year fees related primarily to work completed in conjunction with the development of assays for Roche. The prior year's contract fees were primarily from non-recurring amounts received in connection with our preliminary alliance with Bayer Diagnostics ("Bayer").

Operating Costs and Expenses. Product costs were \$5.9 million (41% of product sales) for fiscal 2002 compared to \$3.6 million (33% of product sales) for fiscal 2001. Included in product costs for fiscal 2002 is a write-off of \$1.1 million of TRICORDER detection modules costs, previously recorded as fixed assets. The TRICORDER modules are incorporated into customers' M-SERIES systems and continue to be utilized by customers to generate ongoing reagent product sales. The impact on prior individual annual periods was not significant. Excluding the \$1.1 million expense, product costs were 33% of product sales for fiscal 2002.

Research and development expenses decreased \$1.3 million (5%) in fiscal year 2002 to \$27.2 million from \$28.5 million in fiscal year 2001. Excluding funding of the MSD joint venture activities prior to the amendment and extension of the MSD joint venture agreements in August 2001, research and development expense was \$24.8 million in 2002 and \$20.2 million in 2001. This increase in research and development expense of \$4.6 million (23%) is primarily due to

ongoing development costs and product enhancements associated with the M-SERIES family of products, development of new assays for the life sciences market and research and development of new systems and technologies, including hospital point-of-care products. We expect research and development costs to increase as product development and core research continue to expand. See "Equity in Loss of Affiliate" below for a discussion of MSD activity in fiscal 2002.

Selling, general and administrative expenses were \$24.2 million in fiscal 2002, an increase of \$7.3 million (43%) over the prior year's total of \$16.9 million. This increase was primarily attributable to additional personnel costs of \$4.6 million required to support the growth in sales and customers, as well as legal and other expenses of \$1.6 million largely associated with the amendment and extension of the MSD joint venture.

Costs related to our litigation with Roche were offset by a settlement payment we received from Roche related to the Delaware litigation during the current year. Under the terms of the settlement, Roche dismissed, with prejudice, all claims against us, reimbursed us for our legal fees incurred in defending this Delaware litigation which totaled approximately \$5.7 million and granted us a fully paid-up, perpetual, worldwide, non-exclusive license (with the right to sublicense) under the patent in suit. Absent this Delaware settlement, costs related to our litigation with Roche increased \$3.2 million (23%) to \$17.0 million in fiscal 2002 from \$13.8 million in fiscal 2001. The increases are attributable to expanded activities in several areas, including pre-trial motions and the preparation and conduct of the trial that ran from October 2001 through January 10, 2002. The increased litigation costs also included financial and legal advisory fees associated with settlement discussions with Roche. With the completion of the Roche trial in January 2002, litigation costs are expected to decline in future periods.

We have engaged a law firm in connection with the Roche litigation and various other matters. A partner of the law firm is one of our directors. We recorded approximately \$11.2 million and \$5.8 million in legal fees with the law firm for the years ended March 31, 2002 and 2001, respectively.

Certain of our officers are also shareholders of several other companies, which are considered our affiliates for the purpose of this discussion. We have shared services arrangements with these affiliated companies. These shared services include accounting, human resources and other administrative services, as well as facility related costs and services. Shared

services costs allocated to affiliated companies, other than MSD, totaled \$1.3 million and \$1.4 million for the years ended March 31, 2002 and 2001, respectively, which reduced certain Operating Costs and Expenses for the respective years. Amounts allocated to affiliated companies are based upon costs incurred by us and are determined through allocation methods that include time spent and square footage utilized. Amounts due from affiliated companies under the shared services arrangements was approximately \$35,000 at March 31, 2002.

Interest and Other Expense. Interest and other expense, net of interest income, were \$5 million in fiscal 2002 and \$4.9 million in fiscal 2001.

Equity in Loss of Affiliate. In August 2001, we entered into agreements with MST continuing MSD, a joint venture formed solely by IGEN and MST in 1995. MSD was formed for the development and commercialization of products utilizing a propriety combination of MST's multi-array technology together with ORIGEN and other technologies owned by us. In conjunction with the amended agreements and the progress made by MSD in the development of its products, we determined that future contributions to MSD would be made based on the future investment benefit to be obtained by us. Our contributions to MSD since July 1, 2001 were recorded as "Investment in Affiliate" and we have recorded 100% of MSD's losses since this date as Equity in Loss of Affiliate. MSD incurred a net loss of \$13.5 million and \$6.2 million for the years ended March 31, 2002 and 2001, respectively. See ITEM 1 "Business—Collaborations," and ITEM 13 "Certain Relationships and Related Transactions."

Net Loss. The net loss for fiscal year 2002 was \$42.5 million (\$2.20 per common share, after consideration of the effect of preferred dividends) compared to a net loss of \$43.3 million (\$2.84 per common share, after consideration of the effect of preferred dividends) in fiscal year 2001. The loss in the prior year comparable period included a one-time, non-cash charge of \$7.0 million (\$0.44 per share) to record the cumulative effect of an accounting change resulting from the adoption of Emerging Issue Task Force Release No. 00-27.

Results of operations in the future are likely to fluctuate substantially from quarter to quarter as a result of various factors, which include the volume and timing of orders for M-SERIES or other products; the timing of instrument deliveries and installations; variations in revenue recognized from royalties and other contract revenues; whether POL customers' contracts are renewed; whether Roche will continue to

supply service and assays to POL customers; the mix of products sold; whether instruments are sold to or placed with customers; the timing of the introduction of new products; competitors' introduction of new products; variations in expenses incurred in connection with the operation of the business, including legal fees, research and development costs and sales and marketing costs; equity in loss of affiliate; manufacturing capabilities; and the volume and timing of product returns and warranty claims.

The Company has experienced significant operating losses each year since inception and expects those losses to continue. Losses have resulted from a combination of lower royalty revenue than the Company believes it is entitled to under the license agreement with Roche, costs incurred in research and development, Roche litigation costs, selling costs and other general and administrative costs. The Company expects to incur additional operating losses as a result of increases in expenses for manufacturing, marketing and sales capabilities, research and product development, general and administrative costs and equity in loss of affiliate, offset in part by lower Roche litigation costs beginning in fiscal 2003. The Company's ability to become profitable in the future will depend, among other things, on its ability to expand the commercialization of existing products; introduce new products into the market; develop marketing, sales and distribution capabilities cost-effectively; and complete new business arrangements.

As of March 31, 2002, we had net operating loss and general business credit tax carryforwards of approximately \$181 million, which expire at various times through 2022, including \$5.2 million during 2003. Our ability to utilize net operating loss and general business credit tax carryforwards may be subject to an annual limitation in future periods pursuant to the "change in ownership rules" under Section 382 of the Internal Revenue Service Code of 1986, as amended.

Years Ended March 31, 2001 and 2000

Revenues. Total revenues for the fiscal year ended March 31, 2001 increased by approximately \$10.7 million or 52% to \$31.4 million from \$20.7 million in fiscal 2000. The revenue growth for fiscal 2001 was due to increases in all revenue categories—product sales, royalty income and contract fees.

Product sales were \$10.9 million in fiscal year 2001, an increase of 41% over the prior year's product sales of \$7.7 million. This growth of \$3.2 million was from the M-SERIES line of instrumentation and consumable life science products (\$1.2 million) as well as new revenue generated from the

sale of clinical diagnostic assays to physician office laboratory (POL) customers in the United States which totaled \$2.0 million in fiscal 2001.

We began serving these POL customers in June 2000 when Roche transferred the customers in order to comply with a court ordered preliminary injunction. The growth of M-SERIES product sales was due to shipments under distribution agreements that we signed during fiscal 2001.

Royalty income was \$16.2 million in fiscal 2001, an increase of 32% over the prior year's royalty income of \$12.2 million. Royalties from Roche represent approximately \$15.3 million (94%) of the total royalty income for fiscal 2001 as compared to approximately \$11.1 million (91%) for fiscal 2000. This increase is attributable to higher Roche sales of its Elecsys product line, which is based on our ORIGEN technology licensed to Roche under a 1992 agreement. We are involved in litigation with Roche arising out of this agreement. One of the disputes in the litigation relates to the computation of royalties to which we believe we are entitled to under the Agreement.

Contract revenue in the current fiscal year increased to \$4.3 million from \$700,000 last year. This increase is attributable to our alliance with Bayer that commenced in fiscal 2001 under which the two companies explored new products for the hospital point-of-care testing market.

Operating Costs and Expenses. Product costs were \$3.6 million (33% of product sales) for fiscal 2001 compared to \$2.3 million (29% of product sales) for fiscal 2000. The decrease in product margins is attributable to M-SERIES retrofit costs of approximately \$500,000 in 2001, offset by a change in product sales mix between lower margin instrumentation (37% of sales in fiscal 2001 versus 39% of sales in fiscal 2000) and higher margin consumable reagents and assays (63% of sales in fiscal 2001 versus 61% of sales in fiscal 2000).

Research and development costs increased \$9.8 million (53%) in fiscal 2001 to \$28.5 million from \$18.7 million in fiscal 2000. This increase was due to personnel and development expenses of \$6.0 million primarily associated with enhancements and development of the M-SERIES line of products, including new assays for life science and hospital point-of-care; and research and development expenses associated with the MSD joint venture which increased \$3.8 million in 2001.

Selling, general and administrative expenses were \$16.9 million in fiscal 2001, an increase of \$2.9 million (20%) over the prior year's total of \$14 million. This increase was due

primarily to higher sales and marketing costs related to expanding the launch of the M-SERIES System throughout the United States, Europe and Japan.

Costs associated with our litigation with Roche increased to \$13.8 million in fiscal 2001 from \$6.3 million in fiscal 2000. This increase was due to expanded activities, including work related to a court-appointed Special Master's examination of Roche's books and records; preparation and presentation of several motions, including motions for summary judgment; preparation for a trial in Delaware in February, 2001; and preparation for and participation in a trial in Maryland that was scheduled to commence in October 2001. The increased litigation costs also include financial and legal advisors' fees associated with settlement discussions.

Interest and Other Expense. Interest expense, net of other income, excluding a non-recurring charge in 2000, increased \$2.6 million in fiscal 2001 due to interest on higher debt balances during the year and a full year's amortization of the detachable warrant value associated with the convertible debentures issued in January 2000. In fiscal 2000, we also recorded a non-cash charge of \$9.6 million related to the beneficial conversion element of the convertible debentures and related warrants.

The convertible debentures have a one-time beneficial conversion feature measured as the difference between the conversion price and the fair value of our common stock at the time of the issuance of debentures.

Cumulative Effect of Accounting Change. During fiscal 2001, we adopted the provisions of Emerging Issues Task Force (EITF) Release No. 00-27, *"Application of EITF Issue No. 98-5, Accounting for Convertible Securities and Beneficial Conversion Features."* This standard established new guidelines for convertible securities and beneficial conversion features. The change in methods resulted in a one-time, non-cash charge that was recorded during the year as a cumulative effect of a change in accounting. Prior year financial statements have not been restated to reflect the change in accounting. The effect of the change on our Statement of Operations for the year ended March 31, 2001 was to increase the net loss by \$7 million (\$0.44 per share).

Net Loss. Excluding the non-recurring, non-cash charge of \$7 million (\$0.44 per share) taken for the cumulative effect of accounting change, the net loss was \$36.3 million (\$2.40 per share, after consideration of the effect of preferred dividends) in fiscal 2001. Including this charge, the net loss was \$43.3 million (\$2.84 per share, after consideration of the effect of preferred dividends). In fiscal 2000, including the non-cash charge, the net loss was \$32.4 million (\$2.24 per share, after consideration of the effect of preferred dividends). Excluding the non-cash charge of \$9.9 million (\$0.64 per share) taken to account for the beneficial conversion element of the convertible debentures and related warrants issued January 2000, the net loss was \$22.5 million (\$1.60 per share, after consideration of the effect of preferred dividends).

Liquidity and Capital Resources

We have financed operations through the sale of preferred and common stock, debt financings and the placement of convertible debentures. In addition, we have received funds from research and licensing agreements, sales of our ORIGEN line of products and royalties from product sales by licensees.

As of March 31, 2002, we had \$74.8 million in cash, cash equivalents and short-term investments, with working capital of \$73.4 million.

Net cash used in operations was \$27.0 million, \$27.4 million and \$23.8 million during the years ended March 31, 2002, 2001 and 2000, respectively. The increase in cash used in 2002 and 2001 from 2000 was due primarily to higher operating losses incurred during each period, as well as increased working capital requirements.

We used approximately \$5.6 million, \$4.9 million, and \$4.6 million of cash for the acquisition of equipment and leasehold improvements during the years ended March 31, 2002, 2001 and 2000, respectively. Our contributions to MSD for the year ended March 31, 2002 totaled \$19.6 million.

We believe material commitments for capital expenditures may be required in a variety of areas, such as product development programs. We have not, at this time, made commitments for any such capital expenditure or secured additional sources to fund such commitments.

Our material future obligations are as follows:

	Years Ended March 31,						2008 and
Contractual Obligations	Total	2003	2004	2005	2006	2007	Thereafter
<i>(in thousands)</i>							
Notes payable	\$ 23,141	\$ 5,077	\$ 5,523	\$ 6,007	\$6,534	\$ —	\$ —
Subordinated convertible debentures	35,000	—	—	35,000	—	—	—
MSD funding commitment	26,955	21,580	5,375	—	—	—	—
Operating and capital leases	8,782	2,304	2,476	2,331	652	357	662
Interest obligations	9,656	3,565	3,112	2,628	351	—	—
Total contractual obligations	\$103,534	\$32,526	\$16,486	\$45,966	\$7,537	\$357	\$662

During August 2001, we entered into agreements with MST continuing MSD, a joint venture formed solely by IGEN and MST in 1995. Under the amended joint venture agreements, we agreed, subject to certain conditions, to fund the joint venture through November 2003. During the 2002 calendar year, we agreed to fund MSD \$21.5 million, subject to a permitted variance of fifteen percent. As of March 31, 2002, the Company satisfied \$5.3 million of this funding commitment. The 2003 calendar year funding commitment is based on an annual budget to be approved by a committee of our Board of Directors. The funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. If the 2003 budget is not approved by our Board of Directors, we would be required to provide transitional funding for an additional six months, estimated at approximately 11.0 million, and under certain conditions, MSD and MST have the right to terminate the joint venture and purchase our interest in MSD at fair market value less certain discounts. The operating and capital lease commitments in the table above exclude amounts expected to be allocated to MSD to meet a portion of our funding commitment.

We have a substantial amount of indebtedness, and there is a possibility that we may be unable to generate cash or arrange financing sufficient to pay the principal of, interest on and other amounts due with respect to indebtedness when due, or in the event any of it is accelerated. In addition, our indebtedness may require that we dedicate a substantial portion of our expected cash flow from operations

to service indebtedness, which would reduce the amount of expected cash flow available for other purposes, including working capital and capital expenditures.

We need substantial amounts of money to fund operations. In this regard, from time to time we have discussions with third parties, including multinational corporations, regarding various business arrangements including distribution, marketing, research and development, joint venture and other business agreements, which could provide for substantial up-front fees or payments. Further, we are considering and evaluating the advisability and feasibility of a variety of financing alternatives, which could be completed in the near term, including issuance of additional debt or equity securities. There can be no assurance that we will successfully complete any of the foregoing arrangements and access to funds could be adversely impacted by many factors, including the results of pending litigation, the volatility of the price of our common stock, continuing losses from operations and other factors. We believe that existing capital resources, together with revenue from product sales, royalties and contract fees will be adequate to fund operations through calendar year 2003. If we are unable to raise additional capital, we may have to scale back, or even eliminate, some programs. Alternatively, we may consider pursuing arrangements with other companies, such as granting licenses or entering into joint ventures, on terms and conditions that may not be favorable to us.

Roche has the right to continue to market its Elecsys products within its licensed field until our right to terminate their license is affirmed on appeal. In connection with the

litigation with Roche, we have notified Roche that the license agreement will terminate upon the appellate court affirming our right to do so.

Termination of the license agreement would have a material adverse effect on our revenues unless, and until, we enter into a strategic partnership with another company that is able to develop and commercialize diagnostic instruments within the field presently licensed to Roche. There can be no assurance that we would be able to enter into such a strategic partnership on favorable terms, if at all.

Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our Consolidated Financial Statements. However, certain accounting policies are particularly important to the portrayal of our financial position and results of operations and require the application of significant judgments by our management. As a result they are subject to an inherent degree of uncertainty. In applying those policies, our management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates.

These estimates are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our customers, and information available from other outside sources, as appropriate. Our significant accounting policies include:

Inventory—We carry our inventory at the lower of cost or market using the first-in, first-out method. We apply judgment in determining the provisions for slow moving, excess and obsolete inventory based on historical experience, anticipated product demand and changes in product design.

Equipment and Leasehold Improvements—Our equipment and leasehold improvements are carried at cost. Depreciation on equipment and furniture is computed over the estimated useful lives of the assets, generally three to five years, using straight line or accelerated methods. Leasehold improvements are amortized on a straight-line basis over the life of the lease. We apply judgment in determining the appropriate useful life of these assets.

Revenue Recognition—We derive revenue principally from three sources: product sales, royalty income and contract fees. Product sales revenue is generally recognized when contractual obligations have been satisfied, title and risk of loss has been transferred to the customer and collection of the resulting receivable is reasonably assured. Rental revenue associated with instruments that are leased is recognized ratably over the life of the lease agreements. We make estimates of allowances for doubtful accounts based on the age of receivables, individual customer profiles and historical experience.

Royalty income is recorded when earned based on information provided by licensees.

Revenue from services performed under contracts is recognized over the term of underlying customer contract or at the end of the contract, when obligations have been satisfied. For services performed on a time and material basis, revenue is recognized upon performance. Amounts received in advance of performance under contracts or commercialization agreements are recorded as deferred revenue until earned.

Capitalized Software Costs—We record software development costs in accordance with SFAS No. 86 "*Accounting for the Costs of Computer Software to be Sold, Leased, or Otherwise Marketed*." We apply our judgment in determining when software being developed has reached technological feasibility, and at that point we would capitalize software development costs. Through March 31, 2002, software development has been substantially completed concurrently with the establishment of technological feasibility, and accordingly, no costs have been capitalized to date.

Equity Accounting—We account for our ownership in the MSD joint venture on the equity method as we have determined that we do not control MSD's operations. Factors considered in determining our level of control include the fact that we own less than 50% of the voting equity interest in MSD; that we do not have exclusive authority over MSD decision making and have no ability

to unilaterally modify the joint venture agreements; and that we have the right to appoint only one out of two seats on MSD's board of managers. See Note 6 of Notes to Consolidated Financial Statements.

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board (FASB) issued SFAS No. 133, *"Accounting for Derivative Instruments and Hedging Activities"* (SFAS 133). SFAS 133 is effective for the years beginning after June 15, 2000 and requires the recognition of derivatives at fair value as either assets or liabilities in the Company's financial statements. The Company has adopted SFAS 133 and determined that it did not have a material effect on the Company's financial position or results of operations for the year ended March 31, 2002.

In June 2001, the FASB issued SFAS No. 143 *"Accounting for Asset Retirement Obligations"* (SFAS 143). SFAS 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS 143 is effective for fiscal years beginning June 15, 2002. The Company does not expect that the implementation of SFAS 143 will have a material effect on the Company's financial position or results of operations.

In October 2001, the FASB issued SFAS No. 144 *"Accounting for the Impairment of Long-Lived Assets"* (SFAS 144) which supersedes SFAS No. 121 *"Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of"* and the accounting and reporting provisions of APB No. 30, *"Reporting the Results of Operations, Reporting and Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions"* for the disposal of segment business. This statement is effective for fiscal years beginning December 15, 2001. SFAS No. 144 retains many of the provisions of SFAS No. 121 but addresses certain implementation issues associated with that Statement. The Company does not expect that the implementation of SFAS 144 will have a material effect on the Company's financial position or results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Changes in interest rates do not affect interest expense incurred on the Company's long-term borrowings because they bear interest at a fixed rate. The principal terms of this debt are as follows:

- Note payable with John Hancock Life Insurance Company: \$30 million principal, seven year, 8.5% Senior Secured Notes secured by future royalty revenue from Roche, maturing in 2006 with quarterly interest only payments through September 2000 and quarterly principal and interest payments through March 2006.
- Subordinated convertible debentures: \$35 million principal, 5% interest maturing January 2005 with semi-annual interest payments in cash or equivalent value of Common Stock.

However, the Company runs a risk that market rates will decline and that the interest rate will exceed those based on the then-current market rate. The Company is currently not using interest rate derivative instruments to manage its exposure to interest rate changes.

Interest income earned on the Company's investment portfolio is affected by changes in the general level of interest rates. The Company has invested its excess cash generally in securities of the U.S. Treasury, money market funds, certificates of deposit and corporate bonds.

The Company invests its excess cash in accordance with a policy objective that seeks to ensure both liquidity and safety of principal. The policy limits investments to certain types of instruments issued by institutions with strong investment grade credit ratings and places restrictions on their terms and concentrations by type and issuer.

The Company is exposed to changes in exchange rates where it sells direct in local currencies, primarily in the United Kingdom and Germany. Certain other foreign sales are denominated in U.S. dollars and have no exchange rate risk. Gains and losses resulting from foreign currency transactions have historically not been material.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS

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We also incorporate herein by this reference Meso Scale Diagnostics, LLC. (A Development Stage Company), Financial Statements at December 31, 2001 and 2000, and for the Three Years Ended In The Period Ended December 31, 2001, and for the period November 30, 1995 (Inception) through December 31, 2001, and Independent Auditors' Report filed as Exhibit 99.1 to this report.


Independent Auditors' Report

To the Stockholders and Board of Directors
of IGEN International, Inc.:

We have audited the accompanying consolidated balance sheets of IGEN International, Inc. (the "Company") as of March 31, 2002 and 2001, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended March 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of March 31, 2002 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2002, in conformity with accounting principles generally accepted in the United States of America.



Deloitte & Touche LLP
McLean, Virginia
May 22, 2002

(June 19, 2002 as to Note 12 of Notes
to Consolidated Financial Statements)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended March 31,		
	2002	2001	2000
<i>(in thousands, except per share amounts)</i>			
REVENUES:			
Product sales	\$ 14,583	\$ 10,913	\$ 7,743
Royalty income	26,768	16,157	12,218
Contract fees	696	4,292	700
Total	<u>42,047</u>	<u>31,362</u>	<u>20,661</u>
OPERATING COSTS AND EXPENSES:			
Product costs	5,937	3,625	2,262
Research and development	27,203	28,497	18,665
Selling, general, and administrative	24,164	16,849	13,989
Litigation costs	11,299	13,782	6,295
Total	<u>68,603</u>	<u>62,753</u>	<u>41,211</u>
LOSS FROM OPERATIONS	<u>(26,556)</u>	<u>(31,391)</u>	<u>(20,550)</u>
OTHER (EXPENSE) INCOME:			
Beneficial conversion feature of debentures	—	—	(9,597)
Interest expense	(6,059)	(6,336)	(3,617)
Other income, net	1,036	1,469	1,359
Total	<u>(5,023)</u>	<u>(4,867)</u>	<u>(11,855)</u>
EQUITY IN LOSS OF AFFILIATE	<u>(10,947)</u>	<u>—</u>	<u>—</u>
LOSS BEFORE CUMULATIVE EFFECT OF ACCOUNTING CHANGE	<u>(42,526)</u>	<u>(36,258)</u>	<u>(32,405)</u>
CUMULATIVE EFFECT OF ACCOUNTING CHANGE	<u>—</u>	<u>(6,995)</u>	<u>—</u>
NET LOSS	<u>(42,526)</u>	<u>(43,253)</u>	<u>(32,405)</u>
PREFERRED DIVIDENDS	<u>(1,402)</u>	<u>(2,052)</u>	<u>(2,137)</u>
NET LOSS ATTRIBUTED TO COMMON STOCKHOLDERS	<u><u>\$(43,928)</u></u>	<u><u>\$(45,305)</u></u>	<u><u>\$(34,542)</u></u>
BASIC AND DILUTED NET LOSS PER COMMON SHARE:			
Loss before cumulative effect of accounting change	\$ (2.20)	\$ (2.40)	\$ (2.24)
Cumulative effect of accounting change	—	(0.44)	—
BASIC AND DILUTED NET LOSS PER COMMON SHARE	<u><u>\$ (2.20)</u></u>	<u><u>\$ (2.84)</u></u>	<u><u>\$ (2.24)</u></u>
WEIGHTED AVERAGE COMMON SHARES			
OUTSTANDING—BASIC AND DILUTED	<u>19,947</u>	<u>15,929</u>	<u>15,415</u>

See notes to consolidated financial statements.

CONSOLIDATED BALANCE SHEETS

March 31,

2002

2001

(in thousands, except share data)

ASSETS

CURRENT ASSETS:

Cash and cash equivalents	\$ 69,541	\$ 15,089
Short-term investments	5,278	—
Accounts receivable, net	10,259	5,863
Inventory	3,331	4,995
Other current assets	1,289	1,834
Total current assets	89,698	27,781

EQUIPMENT AND LEASEHOLD IMPROVEMENTS, NET

7,589 8,085

OTHER NONCURRENT ASSETS:

Investment in affiliate	6,243	—
Restricted cash	1,721	2,120
Other	947	1,147
Total	\$ 106,198	\$ 39,133

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)

CURRENT LIABILITIES:

Accounts payable	\$ 5,830	\$ 10,147
Accrued expenses	2,542	1,942
Accrued wages and benefits	2,359	1,081
Current portion of note payable	5,077	4,668
Deferred revenue	418	794
Obligations under capital leases	56	53
Total current liabilities	16,282	18,685

NONCURRENT LIABILITIES:

Note payable	18,064	23,142
Subordinated convertible debentures	30,032	28,229
Convertible preferred stock dividend payable	3,205	5,121
Deferred revenue	96	273
Obligations under capital leases	—	56
Total noncurrent liabilities	51,397	56,821

COMMITMENTS AND CONTINGENCIES

STOCKHOLDERS' EQUITY (DEFICIT):

Convertible preferred stock, \$0.001 par value, 10,000,000 shares authorized, issuable in Series: Series A, 600,000 shares designated, none issued; Series B, 25,000 shares designated, 8,500 and 18,220 shares issued and outstanding—liquidation value of \$8,500 and \$18,220 plus accrued and unpaid dividends	1	1
Common stock: \$0.001 par value, 50,000,000 shares authorized: 23,064,392 and 17,261,400 shares issued and outstanding	23	17
Additional paid-in capital	242,228	124,816
Stock notes receivable	(3,710)	(3,710)
Accumulated deficit	(200,023)	(157,497)
Total stockholders' equity (deficit)	38,519	(36,373)

TOTAL

\$ 106,198 \$ 39,133

See notes to consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended March 31,		
	2002	2001	2000
<i>(in thousands)</i>			
OPERATING ACTIVITIES:			
Net loss	\$ (42,526)	\$ (43,253)	\$ (32,405)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	5,968	3,955	2,063
Equity in loss of affiliate	10,947	—	—
Beneficial conversion feature of convertible debenture	—	6,995	9,597
Common stock issued in payment of interest	1,757	875	—
Amortization of detachable warrant value	1,419	1,412	300
Expense related to stock options	219	—	—
Changes in assets and liabilities:			
Increase in accounts receivable	(4,396)	(185)	(2,426)
Decrease (increase) in inventory	1,664	(1,932)	(1,608)
Decrease (increase) in other current assets	545	(523)	(536)
Decrease (increase) restricted cash	399	(399)	—
(Decrease) increase in accounts payable and accrued expenses	(2,439)	6,332	1,914
Decrease in deferred revenue	(553)	(725)	(696)
Net cash used for operating activities	<u>(26,996)</u>	<u>(27,448)</u>	<u>(23,797)</u>
INVESTING ACTIVITIES:			
Expenditures for equipment and leasehold improvements	(5,642)	(4,925)	(4,550)
Investments in affiliate	(16,351)	—	—
Sales of short-term investments	—	12,949	10,544
Maturities of short-term investments	—	3,099	5,079
Purchases of short-term investments	(5,278)	(1,559)	(13,529)
Increase in other assets	(85)	—	—
Net cash (used for) provided by investing activities	<u>(27,356)</u>	<u>9,564</u>	<u>(2,456)</u>
FINANCING ACTIVITIES:			
Issuance of common stock, net	116,844	12,870	553
Payments on note payable and capital lease obligations	(4,722)	(2,262)	(119)
Preferred stock dividends paid	(3,318)	(1,311)	(279)
Proceeds from subordinated convertible debentures	—	—	35,000
Disbursements for debt issuance costs	—	—	(1,896)
Increase in restricted cash	—	(321)	(800)
Net cash provided by financing activities	<u>108,804</u>	<u>8,976</u>	<u>32,459</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	<u>54,452</u>	<u>(8,908)</u>	<u>6,206</u>
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	<u>15,089</u>	<u>23,997</u>	<u>17,791</u>
CASH AND CASH EQUIVALENTS, END OF YEAR	<u>\$ 69,541</u>	<u>\$ 15,089</u>	<u>\$ 23,997</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash payments of interest	<u>\$ 2,506</u>	<u>\$ 3,599</u>	<u>\$ 2,583</u>
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Common stock issued in exchange for notes receivable	<u>\$ —</u>	<u>\$ 3,710</u>	<u>\$ —</u>
Accrued preferred dividends	<u>\$ 1,402</u>	<u>\$ 2,052</u>	<u>\$ 2,137</u>
Equipment and leasehold improvements contributed to affiliate	<u>\$ 839</u>	<u>\$ —</u>	<u>\$ —</u>

See notes to consolidated financial statements.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Notes Receivable from Sale of Subscribed Stock	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
<i>(in thousands)</i>								
BALANCE at April 1, 1999	25	\$ 1	15,361	\$15	\$ 87,413	\$ —	\$ (81,839)	\$ 5,590
Issuance of shares of common stock	—	—	107	—	553	—	—	553
Preferred stock converted	(2)	—	110	—	—	—	—	—
Preferred stock, dividends payable	—	—	—	—	(2,137)	—	—	(2,137)
Detachable warrant value	—	—	—	—	6,995	—	—	6,995
Beneficial conversion feature of convertible debenture	—	—	—	—	9,596	—	—	9,596
Net loss	—	—	—	—	—	—	(32,405)	(32,405)
BALANCE at March 31, 2000	23	1	15,578	15	102,420	—	(114,244)	(11,808)
Issuance of shares of common stock	—	—	1,307	2	17,453	(3,710)	—	13,745
Preferred stock converted	(5)	—	376	—	—	—	—	—
Preferred stock, dividends payable	—	—	—	—	(2,052)	—	—	(2,052)
Beneficial conversion feature of convertible debentures	—	—	—	—	6,995	—	—	6,995
Net loss	—	—	—	—	—	—	(43,253)	(43,253)
BALANCE at March 31, 2001	18	1	17,261	17	124,816	(3,710)	(157,497)	(36,373)
Issuance of shares of common stock	—	—	5,107	5	118,596	—	—	118,601
Preferred stock converted	(9)	—	696	1	(1)	—	—	—
Preferred stock, dividends payable	—	—	—	—	(1,402)	—	—	(1,402)
Expense related to stock options	—	—	—	—	219	—	—	219
Net loss	—	—	—	—	—	—	(42,526)	(42,526)
Balance at March 31, 2002	<u>9</u>	<u>\$ 1</u>	<u>23,064</u>	<u>\$23</u>	<u>\$242,228</u>	<u>\$(3,710)</u>	<u>\$(200,023)</u>	<u>\$ 38,519</u>

See notes to consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business Activity—IGEN International, Inc. (the Company) develops, manufactures, and markets products that permit the detection and measurements of biological substances utilizing its patented ORIGEN® technology, which is based on electrochemiluminescence. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, IGEN Europe, Inc. and IGEN International, K.K. All significant inter-company transactions and balances have been eliminated.

Estimates and Reclassifications—The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Certain amounts from the prior years have been reclassified to conform to the current year presentation.

Cash and Cash Equivalents—Cash and cash equivalents include cash in banks, money market funds, securities of the U.S. Treasury, and certificates of deposit with original maturities of three months or less.

Short-Term Investments—Short-term investments consist primarily of corporate debt-securities that are classified as "available for sale." These available for sale securities, which are all due within one year, are accounted for at their fair value and unrealized gains and losses on these securities, if any, are reported as a separate component of stockholders' equity. The Company uses the specific identification method in computing realized gains and losses on the sale of investments which are included in results of operations as generated. Any realized and unrealized gains or losses were not material as of and for the years ended March 31, 2002, 2001 and 2000.

Concentration of Credit Risk—The Company has invested its excess cash generally in securities of the U.S. Treasury, money market funds, certificates of deposit and corporate bonds. The Company invests its excess cash in accordance with a policy objective that seeks to ensure both liquidity and safety of principal. The policy limits investments to certain types of instruments issued by institutions with strong investment grade credit ratings and places restrictions on their terms and concentrations by type and issuer. The Company has not experienced any losses on its investments due to credit risk.

Restricted Cash—The Company has a debt service reserve of approximately \$1.7 million at March 31, 2002 and 2001 that is restricted in use and held in trust as collateral (See Note 4). During fiscal 2002 and 2001, in conjunction with the Roche Diagnostics (Roche) litigation, the Company escrowed approximately \$1.0 million and \$400,000, respectively related to Physician's Office Laboratory sales. The cumulative escrow total of \$1.4 million was released to the Company without restriction upon conclusion of the Roche trial in January 2002 (see Note 12).

Inventory—Inventory is recorded at the lower of cost or market using the first-in, first-out method and consists of the following:

	2002	2001
(in thousands)		
Finished goods	\$ 910	\$1,028
Work in process	1,149	1,912
Raw materials	1,272	2,055
Total	<u>\$3,331</u>	<u>\$4,995</u>

Equipment and Leasehold Improvements—Equipment and leasehold improvements are carried at cost. Depreciation on equipment and furniture is computed over the estimated useful lives of the assets, generally three to five years, using straight-line or accelerated methods. Leasehold improvements are amortized on a straight-line basis over the life of the lease.

Equipment and leasehold improvements consist of the following:

	2002	2001
(in thousands)		
Lab instruments and equipment	\$ 9,076	\$ 8,074
Office furniture and equipment	7,492	6,559
Leasehold improvements	2,864	3,473
	<u>19,432</u>	<u>18,106</u>
Accumulated depreciation and amortization	<u>(11,843)</u>	<u>(10,021)</u>
	<u>\$ 7,589</u>	<u>\$ 8,085</u>

Other Noncurrent Assets—Other noncurrent assets include purchased product technology rights of \$340,000 which are amortized on a straight-line basis over the estimated economic lives of such assets, ranging from five to fourteen years. Accumulated amortization was \$301,000 and \$277,000 at March 31, 2002 and 2001, respectively. Other noncurrent assets also include Deferred Debt Issuance Costs of approximately \$1.4 million which are amortized using the effective interest method over the terms of the debt agreements. Accumulated amortization was \$806,000 and \$545,000 at March 31, 2002 and 2001, respectively.

Capitalized Software Costs—Software development costs incurred subsequent to the establishment of technological feasibility are capitalized in accordance with SFAS No. 86 "Accounting for the Costs of Computer Software to Be Sold, Leased, or Otherwise Marketed." Through March 31, 2002, software development has been substantially completed concurrently with the establishment of technological feasibility, and accordingly, no costs have been capitalized to date.

Evaluation of Long-lived Assets—The Company evaluates the potential impairment of long-lived assets based upon projections of undiscounted cash flows whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. Management believes no impairment of these assets exists as of March 31, 2002 and 2001.

Fair Value of Financial Instruments—The following disclosures of estimated fair value were determined by management using available market information and appropriate valuation methodologies. The fair value of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable, accrued expenses, notes payable, and long-term debt approximate their carrying values. Disclosure about fair values of financial instruments is based on pertinent information available to management as of March 31, 2002. Although management is not aware of any factors that would significantly affect the reasonableness of the fair value amounts, current estimates of fair value may differ significantly from the amounts presented to them.

Warranty Costs—The Company generally warrants its products against defects in materials and workmanship for one year after sale and provides for estimated future warranty costs at the time revenue is recognized. At March 31, 2002 and 2001, accrued product warranty costs totaled \$170,000 and \$225,000, respectively, and are included in accrued expenses.

Comprehensive Income—The Company has no significant elements of comprehensive income other than net loss.

Revenue Recognition—The Company derives revenue principally from three sources: product sales, royalty income and contract fees. Product sales revenue is generally recognized when contractual obligations have been satisfied, title and risk of loss have been transferred to the customer and collection of the resulting receivable is reasonably assured.

Rental revenue associated with instruments that are leased is recognized ratably over the life of the lease agreements. Royalty income is recorded when earned, based on information

provided by licensees. Revenue from services performed under contracts is recognized over the term of the underlying customer contract or at the end of the contract, when obligations have been satisfied. For services performed on a time and material basis, revenue is recognized upon performance. Estimates of allowances for doubtful accounts are based on the age of receivables, individual customer profiles and historical experience.

Amounts received in advance of performance under contracts or commercialization agreements are recorded as deferred revenue until earned.

Foreign Currency—Gains and losses from foreign currency transactions such as those resulting from the settlement of foreign receivables or payables, are included in the results of operations as incurred. These amounts were not material during the years ended March 31, 2002, 2001 and 2000.

Research and Development—Research and development costs are expensed as incurred.

Deferred Income Taxes—Deferred income tax assets and liabilities are computed annually for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

Loss Per Share—The Company uses Statement of Financial Accounting Standard (SFAS) No. 128 "Earnings per Share" for the calculation of basic and diluted earnings per share. The Company's loss has been adjusted by dividends accumulated on the Company's Series B Convertible Preferred Stock for all years presented. Due to the Company's net loss, the potentially dilutive common shares related to outstanding stock options and Series B Convertible Preferred Stock are not included in the calculation of diluted net loss per common share.

Cumulative Effect of Accounting Change—During the year ended March 31, 2001, the Company adopted the provisions of Emerging Issues Task Force (EITF) Release No. 00-27, "Application of EITF Issue No. 98-5, Accounting for Convertible Securities and Beneficial Conversion Features." This standard established new guidelines for convertible securities with beneficial conversion features. The EITF requires conversion options to be calculated using the effective conversion price based on the proceeds allocated to the convertible

instruments. Previously, the Company had calculated the beneficial conversion feature of Subordinated Convertible Debentures, issued in January 2000, using the stated conversion price (See Note 5). The change in methods resulted in a one-time, non-cash charge that was recorded during the year ended March 31, 2001 as a cumulative effect of accounting change. Prior year financial statements have not been restated to reflect the change in accounting. The effect of the change on the Company's Consolidated Statement of Operations for the year ended March 31, 2001 was to increase the net loss by approximately \$7 million (\$0.44 per share). There was no effect on loss before the cumulative effect of the accounting change for the year ended March 31, 2001.

New Accounting Standards—In June 1998, the Financial Accounting Standards Board (FASB) issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" (SFAS 133). SFAS 133 is effective for years beginning after June 15, 2000 and requires the recognition of derivatives at fair value as either assets or liabilities in the Company's financial statements. The Company has adopted SFAS 133 and determined that it did not have a material effect on the Company's financial position or results of operations for the year ended March 31, 2002.

In June 2001, the FASB issued SFAS No. 143 "Accounting for Asset Retirement Obligations" (SFAS 143). SFAS 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS 143 is effective for fiscal years beginning after June 15, 2002. The Company does not expect that the implementation of SFAS 143 will have a material effect on the Company's financial position or results of operations.

In October 2001, the FASB issued SFAS No. 144 "Accounting for the Impairment of Long-Lived Assets" (SFAS 144) which supersedes SFAS No. 121 "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of" and the accounting and reporting provisions of APB No. 30, "Reporting the Results of Operations, Reporting and Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions" for the disposal for a segment of business. This statement is effective for fiscal years beginning after December 15, 2001. SFAS No. 144 retains many of the provisions of SFAS No. 121 but addresses certain implementation issues associated with that Statement. The Company does not expect

that the implementation of SFAS 144 will have a material effect on the Company's financial position or results of operations.

2. LICENSE AND RESEARCH AGREEMENTS

In 1992, the Company entered into an agreement with Roche Diagnostics, under which that company was granted rights to develop and market certain clinical diagnostic systems worldwide based on the Company's *ORIGEN* technology. Under the terms of the agreement, the Company has received license payments of \$50 million. This agreement also provides the Company with additional payments for certain product development work, as well as royalties on product sales. The Company is currently in litigation with Roche (See Note 12).

During 1993, the Company entered into a \$20 million license and stock purchase agreement with BioMerieux (formerly Organon Teknika, B.V.). Under this agreement, the Company sold 346,135 shares of Common Stock, granted a license to develop and market certain diagnostic systems worldwide utilizing the Company's *ORIGEN* technology and agreed to invest \$5 million in research and development under a joint development program. Among other things, the agreement provides for royalty payments to the Company on product sales and for product supply arrangements between the parties. The Company recorded royalty income of \$252,000, \$276,000 and \$495,000 for the fiscal years ended March 31, 2002 2001, and 2000, respectively.

During 1990, the Company granted a license to Eisai Co., Ltd., to market in Japan certain clinical diagnostic systems based on the Company's *ORIGEN* technology. The agreement provided license fees of \$8 million tied to the achievement of product development milestones. This agreement also provides for royalty payments to the Company on product sales. In 1997, the Company received \$2.8 million as an advance royalty payment of which approximately \$2.7 million has been recognized as revenue through March 31, 2002.

3. STOCKHOLDERS' EQUITY (DEFICIT)

Convertible Preferred Stock—The Company has issued 25,000 shares of Series B Convertible Preferred Stock (Series B) with a stated value of \$1,000 per share which are convertible into shares of Common Stock of the Company at a rate of \$13.96 per share.

As of March 31, 2002 and 2001, outstanding Series B shares totaled 8,500 and 18,220, which had liquidation values of \$8.5 million and \$18.2 million, respectively, plus accrued and unpaid dividends. A total of 16,500 shares of Series B have been converted into 1,181,948 shares of Common Stock through March 31, 2002. Upon conversion, the Company paid dividends of \$3.3 million, \$1.3 million and \$279,000 during the years ended March 31, 2002, 2001 and 2000, respectively. The remaining 8,500 unconverted Series B shares may be converted into 608,883 shares of Common Stock. The Series B holders are entitled to a dividend payment of 7.75% compounded annually on the stated value of the stock. The Company may elect to make the dividends payable in common shares at a rate of \$13.96 per share, rather than making the dividend payment in cash. If the Company elected to pay such dividends in shares of Common Stock, it may issue up to 760,430 shares to the holders of Series B. On May 22, 2002, the Company notified holders of the outstanding Series B shares that it planned to redeem those shares on July 9, 2002 for their liquidation value. Holders may elect to convert their Series B shares into Common Stock of the Company before the Company redeems the stock.

Shareholder Rights Plan—In 1996, the Board of Directors adopted a shareholder rights plan and declared a dividend of one preferred share purchase right for each outstanding share of the Company's Common Stock (par value \$.001 per share). Each Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value \$.001 per share, at a price of \$65.00 per one one-hundredth of a Preferred Share, subject to adjustment. The Rights will be

exercisable only if a person or group (other than certain affiliates of the Company) acquires 15% or more of the Common Stock or announces a tender offer that would result in that person or group acquiring 15% or more of the Common Stock. Once exercisable, the Plan allows stockholders (other than the acquirer) to purchase Common Stock or securities of the acquirer having a then current market value of two times the exercise price of the Right. The Rights are redeemable for \$.01 per Right (subject to adjustment) at the option of the Board of Directors. Until a right is exercised, the holder of the Right has no rights as a stockholder of the Company. The Rights will expire in 2006 unless redeemed by the Company prior to that date.

Stock Option Plan—The Company has adopted the 1994 Stock Option Plan under which 2,500,000 shares of Common Stock have been reserved for issuance upon exercise of options granted to employees or consultants and the 1994 Non-Employee Directors Stock Option Plan under which 150,000 shares of Common Stock have been reserved for issuance upon exercise of options granted to Non-Employee Directors. The 1994 Stock Option Plan replaced the 1985 Stock Option Plan which expired in February 1995 and continues to have unexercised options. The option plans provide for the granting of both incentive stock options intended to qualify as such under Section 422 of the Internal Revenue Code of 1986, as amended, and other stock options that do not so qualify.

In fiscal 2002, the Company adopted the 2001 Broad Based Option Plan under which 250,000 shares of Common Stock have been reserved for issuance under the plan.

A summary of the option activity is as follows:

	2002		2001		2000	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	2,244	\$ 9.40	1,652	\$ 7.78	1,805	\$7.77
Granted	79	25.38	867	14.98	—	—
Exercised	(957)	5.27	(241)	17.06	(81)	6.81
Cancelled/forfeited	(30)	11.64	(34)	9.32	(72)	8.62
Outstanding at year-end	1,336	<u>\$13.31</u>	2,244	<u>\$ 9.40</u>	1,652	<u>\$7.78</u>
Options exercisable at year-end	735		1,414		1,372	
Options available for future grant	1,073		134		151	
Weighted average fair value of options granted during the year		\$15.68		\$ 9.66		\$ —

The following table summarizes information about stock options outstanding at March 31, 2002 (shares in thousands):

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 4.57–\$ 7.50	360	4.66	\$ 5.63	348	\$ 5.62
8.75– 11.56	388	7.31	10.92	195	10.36
12.75– 18.00	47	6.71	14.66	25	14.25
18.75– 27.52	541	8.23	20.01	167	19.39
4.57– 27.52	<u>1,336</u>	<u>6.95</u>	<u>\$13.31</u>	<u>735</u>	<u>\$10.30</u>

In August 2000, the Company granted 75,000 non-qualified stock options in connection with a consulting arrangement for services to be provided to the Company. The consultant is also the sole owner of MST (see Note 6). As a result of certain events in fiscal 2002 and pursuant to Financial Accounting Standards Board Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation—an Interpretation of APB Opinion No. 25" and EITF 96-18, "Accounting for Equity Instruments That are Issued To Other Than Employees For Acquiring, or in Conjunction with Selling, Goods or Services." The Company began recognizing expense on a monthly basis as the options are earned and vest, based upon fair value calculated in accordance with the Black-Scholes option pricing model. Changes in the fair market value of the unvested options will result in changes in future expense recognition. The options vest ratably over a five-year period through August 2005 and the Company recorded \$219,000 of non-cash expense during the year ended March 31, 2002.

As permitted by SFAS 123, the Company continues to measure compensation expense for its stock-based employee compensation plans using the intrinsic value method prescribed by Accounting Principals Board Statement No. 25, "Accounting for Stock Issued to Employees."

Pro forma disclosures of the effect on net loss and loss per share as if the fair value-based method prescribed by SFAS 123 had been applied is provided in the table below.

	2002	2001	2000
Net loss (in thousands)			
As reported	\$(42,526)	\$(43,253)	\$(32,405)
Pro forma	(45,974)	(46,142)	(34,455)
Basic loss per share			
As reported	\$ (2.20)	\$ (2.84)	\$ (2.24)
Pro forma	(2.38)	(3.03)	(2.37)

The fair value of the option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	2002	2001	2000
Expected dividend yield	0%	0%	0%
Expected stock price volatility	71%	71%	68%
Risk-free interest rate	4.3%	5.5%	6.3%
Expected option term	5 Years	5 Years	5 Years

Stock Notes Receivable—In connection with the exercise of stock options by officers in July 2000, the Company granted loans in the principal amounts of \$3.7 million, maturing in July 2008. The loans are 6.62% simple interest (paid annually), full recourse loans against all assets of the borrowers, collateralized by the pledge of 180,000 shares of the Company's Common Stock owned by the borrowers.

Equity Financings—The Company has completed stock purchase and sale agreements with certain institutional investors for the private placement of the Company's common stock. During the years ended March 31, 2002 and 2001, the Company sold 4,093,698 and 1,000,975 shares of its common stock for aggregate net proceeds of approximately \$112.2 million and \$12.5 million, respectively.

4. NOTE PAYABLE

In March 1999, the Company entered into a debt financing under a Note Purchase Agreement (Note) from which the Company received \$30 million. The seven year, 8.5% Senior Secured Notes mature in 2006 with principal and interest installments of \$1.7 million due quarterly through March 2006. The Company is required to make note principal and interest payments of approximately \$6.9 million in each fiscal year through 2006.

Collateral for the debt is represented by royalty payments and rights of the Company to receive monies due pursuant to the Company's license agreement with Roche. Additional collateral is represented by restricted cash (see Note 1), which had a balance of approximately \$1.7 million at March 31, 2002 and 2001. Covenants within the Note include compliance with annual and quarterly Royalty Payment Coverage Ratios, which are tied to royalty payments and debt service.

5. SUBORDINATED CONVERTIBLE DEBENTURES

In January 2000, the Company completed a placement of \$35 million principal amount of Subordinated Convertible Debentures. The 5% debentures, if not converted, mature January 2005 with semi-annual interest payments to be made in cash or an equivalent value of Common Stock. The debentures are immediately convertible into 1,129,032 shares of the Company's Common Stock, which represents a \$31 per share conversion price.

The debentures had a one-time beneficial conversion feature totaling \$9.6 million measured as the difference between the conversion price of \$31 per share and the fair value of the Common Stock at the time of the issuance of the debentures. This beneficial conversion feature was recorded as a one-time, non-cash charge to interest expense in fiscal 2000. See Note 1, "Cumulative Effect of Accounting Change" for a description of the effect of a change in accounting in fiscal 2001 related to the convertible debentures.

As part of this financing, the Company also issued detachable warrants to purchase 282,258 shares of Common Stock with an exercise price of \$31 per share. Using the Black-Scholes model and the relative fair value of the warrants and the debentures at the time of issuance, these warrants were valued at approximately \$7.0 million. The detachable warrant value has been recorded as a reduction of the face value of the convertible debentures. Costs associated with placing the debentures totaling approximately \$1.9 million, were deferred and have been netted against the recorded convertible debenture balance. The convertible debenture discount consisting of the warrant value and debt issuance costs is being amortized over the five-year life of the debentures. All warrants remain outstanding as of March 31, 2002.

6. MESO SCALE DIAGNOSTICS JOINT VENTURE

During August 2001, the Company entered into agreements with Meso Scale Technologies, LLC. ("MST") continuing Meso Scale Diagnostics, LLC. ("MSD"), a joint venture formed solely by the Company and MST in 1995. MSD was formed for the development and commercialization of products utilizing a proprietary combination of MST's multi-array technology together with ORIGEN and other technologies owned by the Company. MST is a company established and wholly-owned by the son of IGEN's Chief Executive Officer. Under most circumstances, significant MSD governance matters require the approval of both the Company and MST.

Under the amended agreements that were negotiated by an independent committee of the Company's Board of Directors, the Company holds a 31% voting equity interest in MSD. It also owns 100% of the non-voting equity interest in MSD and is entitled to a preferred return on \$36.4 million of the funds previously invested in MSD through March 31, 2002 and on additional funds it invests thereafter. This preferred return would be payable out of a portion of both future profits and certain third-party financings, before any payments are made to other equity holders. MST owns the remaining 69% of the voting equity interest in MSD. The Company agreed, subject to certain conditions, to fund the joint venture through November 2003. During the 2002 calendar year, the Company agreed to fund MSD \$21.5 million, subject to a permitted variance of fifteen percent. As of March 31, 2002, the Company has satisfied \$5.3 million of this funding commitment. The 2003 calendar year funding commitment would be based on an annual budget to be approved by a committee of the Company's Board of Directors. The funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities.

If the 2003 budget is not approved by our Board of Directors, the Company would be required to provide transitional funding for an additional six months, estimated to be approximately \$11.0 million, and under certain conditions, MSD and MST have the right to terminate the joint venture and purchase our interest in MSD at fair market value less certain discounts.

MST and MSD have the right to terminate the joint venture prior to November 2003 under certain circumstances, including a change in control of the Company, as defined. Upon termination, expiration or non-renewal of the joint venture agreement, MSD and MST have the right to purchase the Company's interest in MSD at fair market value less certain discounts.

Since inception of the joint venture, the Company has utilized the equity method to account for the investment. In conjunction with the amended agreements and the progress made by MSD in the development of its products, the Company has determined that future contributions to MSD would be made based on the future investment benefit to be obtained by the Company. Therefore, the Company's share of MSD losses, since July 1, 2001, totaling \$10.9 million, were recorded as Equity in Loss of Affiliate. Prior to this date, the Company accounted for its equity investments in MSD as research and development funding and accordingly, recorded all MSD investments as research and development expenses as incurred. These research and development expenses totaled \$2.4 million, \$8.3 million and \$4.5 million for the years ended March 31, 2002, 2001 and 2000. During the years ended March 31, 2002, 2001 and 2000, operating costs allocated to MSD by the Company in connection with shared personnel and facilities totaled \$11.4 million, \$5.6 million and \$4.1 million, respectively. Since July 1, 2001, these allocated operating costs reduced certain Operating Costs and Expenses and increased Equity in Loss of Affiliate in the accompanying Consolidated Statements of Operations. At March 31, 2002, the Company's Investment in Affiliate totaled \$6.2 million.

Summarized financial information for MSD (unaudited) is as follows (in thousands):

	Years Ended March 31,		
	2002	2001	2000
Operating expenses	\$13,560	\$6,185	\$4,282
Net loss	13,541	6,185	4,282

	March 31,	
	2002	2001
Current assets	\$4,571	\$ 41
Total assets	8,305	1,430
Current liabilities	885	140
Total liabilities	931	140
Total members' equity	7,374	1,290

7. INCOME TAXES

For the years ended March 31, 2002, 2001 and 2000, the Company recorded no federal or state income tax expense and did not owe or pay federal or state tax, as calculated by applying statutory rates to pretax income.

As of March 31, 2002, the Company has available for income tax reporting purposes net operating loss and general business credit carryforwards approximating \$175.4 million and \$5.8 million, respectively. Approximately \$9.7 million of the net operating loss carryforward results from the exercise of nonqualified stock options. Utilization of net operating loss carryforwards related to stock-based compensation will result in the benefit being credited to stockholders' equity.

The use of the Company's net operating loss carryforward may be significantly reduced if substantial changes in stock ownership take place. The carryforwards expire as follows (in thousands):

2003	\$ 5,242
2004	6,847
2005	3,297
2006	170
2007	198
2008 through 2022	165,395
Total	<u>\$181,149</u>

The approximate tax effects of temporary differences that gave rise to the Company's deferred tax assets are as follows:

	2002	2001
(in thousands)		
Deferred tax assets		
Deferred revenue	\$ 198	\$ 412
Investment in affiliate	1,674	—
Net operating loss and tax credit carryforwards	73,475	54,833
Other	1,020	624
Total deferred tax asset	76,367	55,869
Less: valuation allowance	(76,367)	(55,869)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Due to uncertainties surrounding realizability, a valuation allowance equal to the total net deferred tax assets has been provided as of March 31, 2002 and 2001. The increase in the valuation allowance on the deferred tax asset was \$20.5 million and \$14.9 million for the years ended March 31, 2002 and 2001, respectively.

A reconciliation of the statutory federal income tax rate with the Company's effective income tax rate is as follows:

	2002	2001	2000
Statutory federal rate	(34.0%)	(34.0%)	(34.0%)
State income taxes, net of valuation allowance	0.0	0.0	0.0
Beneficial conversion	—	5.5	10.1
Valuation allowance	33.7	28.4	23.8
Other	0.3	0.1	0.1
Effective tax rates	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

8. EMPLOYEE SAVINGS PLAN

The Company has an Employee Savings Plan qualifying under Section 401(k) of the Internal Revenue Code and subject to the Employee Retirement Income Security Act of 1974, as amended. The Company made discretionary contributions of \$237,000, \$299,000 and \$240,000 for the years ended March 31, 2002, 2001 and 2000, respectively.

The Company is not obligated under any postretirement benefit plan.

9. RELATED PARTIES

Certain officers of the Company are also shareholders of several other companies, which are considered affiliates of the Company for the purpose of this disclosure. The Company has shared services arrangements with these affiliated companies. These shared services include accounting, human resources and other administrative services, as well as facility related costs and services. Shared services costs allocated to affiliated companies, other than to MSD (See Note 6), totaled \$1.3 million, \$1.4 million, and \$1.8 million for the years ended March 31, 2002, 2001 and 2000, respectively, which reduced certain Operating Costs and Expenses in the accompanying Consolidated Statements of Operations for the respective years. Amounts allocated to affiliated companies are based upon costs incurred by the Company and are determined through allocation methods that include time spent and square footage utilized. Amounts due from affiliated companies under the shared services arrangements, were approximately \$35,000 and \$20,000 at March 31, 2002 and 2001, respectively.

The Company has engaged a law firm in connection with the Roche litigation and various other matters. A partner of the law firm is a director of the Company. The Company recorded approximately \$11.2 million, \$5.8 million and \$2.1 million in legal fees with the law firm for the years ended March 31, 2002, 2001 and 2000, respectively. Amounts due to the law firm totaled \$1.7 million and \$2.1 million as of March 31, 2002 and 2001, respectively.

The Company has licensed certain diagnostic technologies from affiliated companies and has licensed certain pharmaceutical technologies to affiliated companies. No royalties have ever been earned or accrued under these license agreements.

10. COMMITMENTS

Capital Leases—The Company is obligated under capital lease agreements for certain equipment. These agreements expire during the year ending March 31, 2003. The aggregate discounted lease payments are recorded as a liability, and the fair market value of the related leased assets are capitalized and amortized over the assets estimated useful lives. Total assets capitalized pursuant to such agreements were approximately \$350,000 at March 31, 2002 and 2001 with accumulated amortization totaling approximately \$307,000 and \$285,000 at March 31, 2002 and 2001, respectively.

Operating Leases—The Company leased office, laboratory and manufacturing facilities pursuant to operating leases expiring at various times through fiscal 2010. Rent expense for facility and equipment operating leases totaled approximately \$2.6 million, \$2.4 million and \$1.8 million for the years ended March 31, 2002, 2001 and 2000, respectively.

At March 31, 2002, the future minimum operating lease payments are as follows (in thousands):

2003	\$2,777
2004	2,608
2005	2,331
2006	652
2007	357
2008 and thereafter	662
Total	<u>\$9,387</u>

11. SEGMENT INFORMATION

The Company operates in one business segment. It is engaged in the development and commercialization of ORIGIN-based products for the detection and measurement of biological substances. Product sales by region are as follows (in thousands):

	2002	2001	2000
United States	\$10,050	\$ 6,349	\$6,186
United Kingdom	2,456	612	566
All other foreign	2,077	3,952	991
Total	<u>\$14,583</u>	<u>\$10,913</u>	<u>\$7,743</u>

Substantially all assets are held in the United States.

Except for royalty and contract revenue from Roche, no single customer accounted for more than 10% of total revenue. Revenue from Roche totaled 63%, 50% and 54% of total revenues for the years ended March 31, 2002, 2001 and 2000, respectively. Roche is the only customer with an account receivable balance that exceeds 10% of total outstanding receivables. The amount receivable from Roche totaled 65% and 68% of total accounts receivable at March 31, 2002 and 2001, respectively.

12. LITIGATION

Roche

In 1997, the Company filed a lawsuit against Roche Diagnostics GmbH (formerly Boehringer Mannheim GmbH) in the Southern Division of the United States District Court for the District of Maryland. The lawsuit arises out of a 1992 License and Technology Development Agreement (the "Agreement"), under which the Company licensed to Roche certain rights to develop and commercialize diagnostic products based on the Company's *ORIGEN* technology. In its lawsuit, the Company alleged that Roche failed to perform certain material obligations under the Agreement and engaged in unfair competition against the Company.

The jury trial in this litigation was completed in January 2002, and in February 2002, the Court issued a final order of judgment that awarded the Company \$105 million in compensatory damages and \$400 million in punitive damages, confirmed the Company's right to terminate the Agreement, and directed and commanded Roche to grant to the Company for use in its retained fields a license to certain improvements developed by Roche under the Agreement. Roche was also ordered, at its sole cost and expense, to deliver such improvements to the Company and to provide all other information and materials required or necessary to enable the Company to commercialize these improvements. Improvements, as defined in the judgment, include Roche's Elecsys® 1010, 2010 and E170 lines of clinical diagnostic immunoassay analyzers, the tests developed for use on those systems, and Roche's nucleic acid amplification technology called PCR. The jury further concluded that Roche violated its duty to the Company of good faith and fair dealing, engaged in unfair competition against the Company, and materially breached the Agreement.

The judgment bars Roche from marketing, selling, placing or distributing outside of its licensed field any products, including its Elecsys diagnostics product line, that are based on the Company's *ORIGEN*® technology. While the Company has voluntarily agreed not to terminate the Agreement until

an appellate court determines that it is entitled to do so, the Company has notified Roche that the Agreement will terminate automatically once the Company's right to do so is affirmed by the appellate court. Upon termination, Roche will be prohibited from commercializing all *ORIGEN*-based products in all fields. At that time, the Company will be free to operate, either independently or with new partners, in all fields, including those currently licensed to Roche.

Roche filed counterclaims against the Company alleging, among other things, that IGEN breached the Agreement by permitting Eisai Co., Ltd., another of the Company's licensees, to market certain *ORIGEN*-based products in Japan. The final judgment issued in the litigation found in the Company's favor and against Roche on all of Roche's counterclaims, except for one in which the Company was ordered to pay \$500,000.

Roche has filed a notice of appeal with the U.S. Court of Appeals for the Fourth Circuit. In connection with the filing of that appeal, Roche posted a \$600 million bond to support its financial obligations to the Company under the judgment. During the appeal process, Roche is obligated to continue to comply with the terms of the license agreement, including its obligation to continue to pay the Company royalties on Roche's sales of royalty-bearing products and to share and deliver improvements. Roche's obligation to pay the \$505 million of monetary damages awarded to the Company is suspended until completion of the appeal process. The Company has also filed a notice of appeal on the judgment issued under the Roche counterclaim. Although the Company will vigorously oppose Roche's appeal, Roche may ultimately prevail in its attempt to modify or overturn the judgment issued in this litigation.

In 1998, a subsidiary of Ares-Serono ("Serono") filed a patent infringement claim against the Company, Roche and BioMerieux (formerly Organon Teknika) in the U.S. District Court, District of Delaware. The action claimed that a Serono patent was being infringed by the parties. Subsequently, F. Hoffmann LaRoche, Ltd., a member of the Roche family of companies, acquired the patent from Serono and continued in Serono's place to assert the infringement claim against the Company and BioMerieux. A trial was held on this matter during February 2001. During November 2001, a settlement was reached between the Company and Roche under which Roche dismissed with prejudice all claims against the Company, paid the Company \$5.7 million as reimbursement for legal fees incurred in the litigation and granted the Company a fully paid-up, perpetual, worldwide, non-exclusive license (with the right to grant sublicenses) to the patent in suit.

Hitachi

In 1997, IGEN International K.K., a Japanese subsidiary of the Company, filed a lawsuit in Tokyo District Court against Hitachi Ltd. ("Hitachi"). The lawsuit sought to enjoin Hitachi from infringing a license registration held by IGEN K.K. and Eisai Co., Ltd., a company to which IGEN has licensed ORIGEN technology rights. The lawsuit requested injunctive relief preventing Hitachi from manufacturing, using or selling the Elecsys 2010, which incorporates the Company's patented ORIGEN technology, in Japan. On June 13, 2002, Hitachi and the Company reached an agreement to settle this litigation and the case has been dismissed.

Other Proceedings

In February 2001, Brown Simpson Strategic Growth Fund L.P., Brown Simpson Strategic Growth Fund, Ltd. and Brown Simpson Partners I (collectively "Brown Simpson") initiated a shareholder derivative lawsuit for and on behalf of the shareholders of the Company in the Circuit Court for Montgomery County, Maryland against four of the Company's current directors, two former directors, three executive officers and the Company as a nominal defendant.

In the complaint, Brown Simpson alleged breach of fiduciary duties by the named individual defendants in connection with transactions between the Company and other entities in which certain directors and officers are alleged to have an interest, including the Meso Scale Diagnostics, LLC. joint venture.

In March 2001, a second shareholder derivative lawsuit was filed by Laurence Paskowitz in the Circuit Court for Montgomery County, Maryland with allegations substantially

the same as those set forth in the complaint filed by Brown Simpson. The complaint was later amended to add direct claims against the defendants and to seek class action certification for those direct claims.

Both lawsuits sought principally the following: that the defendants hold in trust and be required to account for and restore to the Company damages that IGEN has allegedly sustained by reason of the allegations and relief relating to board and management composition. The Paskowitz complaint also sought damages for a class of IGEN shareholders for the direct claims against the individual defendants. The complaints did not include any claims against the Company.

The Company and the individual defendants filed motions to dismiss or, in the alternative, for summary judgment in both lawsuits. On May 15, 2002, following hearings in December 2001 and March 2002, the court issued an opinion and order dismissing all claims asserted against all of the defendants. On June 19, 2002, an appeal was filed by one of the plaintiffs. The Company believes that the claims are without merit and it intends to vigorously oppose the appeal filed in this case.

The Company is involved, from time to time, in various other legal proceedings arising in the ordinary course of business. In the opinion of management, the Company does not believe that any legal proceedings described as Other Proceedings will have a material adverse impact on its financial position, results of operations or cash flows.

13. VALUATION AND QUALIFYING ACCOUNTS

The following table sets forth activity in the Company's allowance for doubtful accounts (in thousands):

For the Years Ended March 31,	Balance at Beginning of Period	Charges to Expense	Deductions	Balance at End of Period
2000	\$46	\$ 18	\$ —	\$64
2001	64	135	(169)	30
2002	30	60	(1)	89

14. QUARTERLY OPERATING RESULTS (UNAUDITED)

For the year ended March 31, 2002	First	Second	Third	Fourth
<i>(in thousands, except per share data)</i>				
Revenue ⁽¹⁾	\$ 8,258	\$ 9,396	\$ 10,424	\$ 13,969
Loss from operations ^(2,3,4)	(10,619)	(7,636)	(4,184)	(4,117)
Net loss ⁽⁴⁾	(11,917)	(12,103)	(9,227)	(9,279)
Basic and diluted loss per share	(0.69)	(0.64)	(0.48)	(0.43)
For the year ended March 31, 2001	First	Second	Third	Fourth
<i>(in thousands, except per share data)</i>				
Revenue ⁽⁵⁾	\$ 7,574	\$ 6,570	\$ 8,500	\$ 8,718
Loss from operations	(4,013)	(7,642)	(7,807)	(11,929)
Loss before cumulative effect of accounting change	(5,131)	(8,763)	(9,047)	(13,317)
Cumulative effect of accounting change ⁽⁶⁾	—	—	(6,995)	—
Net loss	(5,131)	(8,763)	(16,042)	(13,317)
Loss before cumulative effect of accounting change (per share)	—	(0.60)	—	—
Cumulative effect of accounting change (per share)	—	—	(0.44)	—
Basic and diluted loss per share	(0.36)	(0.59)	(1.04)	(0.83)

(1) Revenues for the first and fourth quarters includes \$550,000 and \$3.2 million, respectively of Roche royalties relating to modifications made by Roche to their methodology for computing royalties.

(2) Operating costs and expenses for the third quarter have been reduced by a reimbursement of \$5.7 million resulting from the settlement of the Delaware litigation with Roche.

(3) Operating costs and expenses for the fourth quarter includes a write-off of \$1.1 million of TRICORDER detection modules previously recorded as fixed assets. The impact on individual prior interim and annual periods was not significant.

(4) See Note 6 of Notes to Consolidated Financial Statements for a description of the recording of losses related to the MSD investment.

(5) Revenues for the first and fourth quarters includes \$1.8 million and \$2.0 million, respectively related to contract revenue from the alliance with Bayer Diagnostics.

(6) See Note 1 of Notes to Consolidated Financial Statements for a description of the cumulative effect of accounting change.

The sum of quarterly per share amounts may not be equal to per share amounts reported for year-to-date periods. This is due to changes in the number of weighted average shares outstanding and the effects of rounding for each period.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

PART III

Certain information required by Part III is omitted from this Report in that the Company will file a definitive proxy statement pursuant to Regulation 14A (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Report, and certain information included therein is incorporated herein by reference. Only those sections of the Proxy Statement which specifically address the items set forth herein are incorporated by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE COMPANY

(a) **Directors.** The information with respect to directors required under this item is incorporated herein by reference to the section captioned "Election of Directors" in the Company's Proxy Statement with respect to the Annual Meeting of Shareholders to be held on August 28, 2002.

(b) **Executive Officers and Significant Employees.** The information with respect to executive officers and significant employees required under this item is incorporated herein by reference to Part I, Item 1, Business—Executive Officers of the Company, and —Other Key Management of this report.

ITEM 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated herein by reference to the sections entitled "Election of Directors—Compensation for Directors," and —Compensation Committee Interlocks and Insider Participation," and "Executive Compensation," in the Company's Proxy Statement with respect to the Annual Meeting of Shareholders to be held on August 28, 2002.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDERS MATTERS

The information required under this item is incorporated herein by reference to the section entitled "Security Ownership of Certain Beneficial Owners and Management" in the Company's Proxy Statement with respect to the Annual Meeting of Shareholders to be held on August 28, 2002.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required under this item is incorporated herein by reference to the section entitled "Certain Transactions" in the Company's Proxy Statement with respect to the Annual Meeting of Shareholders to be held on August 28, 2002.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a)(1) Index to Financial Statements

The financial statements listed in the Index to Financial Statements are filed as part of this Annual Report on Form 10-K. See ITEM 8—Consolidated Financial Statements and Supplementary Data.

(a)(2) Index to Financial Statement Schedules

All schedules are omitted because they are not applicable, or not required, or because the required information is included in the financial statements or notes thereto.

(a)(3) Index to Exhibits

The Exhibits filed as part of this Form 10-K are listed on and incorporated by reference to the Exhibit Index immediately following the Signature page to this Form 10-K.

(b) Reports on Form 8-K

The Company filed reports on Form 8-K under Item 5, Other Events on January 11, 2002; February 20, 2002; March 15, 2002.

(c) Exhibits

The Exhibits filed as part of this Form 10-K are listed on and incorporated by reference to the Exhibit Index immediately following the Signature page to this Form 10-K.

(d) Financial Statement Schedules

All schedules are omitted because they are not applicable, or not required, or because the required information is included in the financial statements or notes thereto.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

June 28, 2002
IGEN International, Inc.
By: /s/ Samuel J. Wohlstadter
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Samuel J. Wohlstadter</u> Samuel J. Wohlstadter	Chief Executive Officer (Principal Executive Officer); Director	June 28, 2002
<u>/s/ George V. Migausky</u> George V. Migausky	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	June 28, 2002
<u>/s/ Richard J. Massey</u> Richard J. Massey	President, Chief Operating Officer; Director	June 28, 2002
<u>/s/ Richard Cass</u> Richard Cass	Director	June 28, 2002
<u>/s/ Anthony Rees</u> Anthony Rees	Director	June 28, 2002
<u>/s/ Robert Salsmans</u> Robert Salsmans	Director	June 28, 2002
<u>/s/ Joop Sistermans</u> Joop Sistermans	Director	June 28, 2002

Index to Exhibits

Exhibit Number	Description of Document	Exhibit Number	Description of Document
2.1 ⁴	Agreement and Plan of Merger effective November 19, 1996 (by virtue of a reincorporation), by and between IGEN, Inc., a California corporation and IGEN International, Inc. a Delaware corporation.	10.4 ¹	Supplemental Agreement between Eisai Co., Ltd. and the Company.
3.1 ⁴	Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on August 30, 1996.	10.5 ^{3*}	License and Development Technology Agreement between the Company and Boehringer Mannheim GmbH dated September 23, 1992.
3.2 ⁴	Certificate of Designation of Series A Junior Participating Preferred Stock, as filed with the Secretary of State of the State of Delaware on November 18, 1996.	10.6 ²	Advanced Royalty Agreement between the Company and Boehringer Mannheim GmbH dated January 9, 1997.
3.3 ⁸	Certificate of Designation of Series B Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware on December 18, 1997.	10.7 ³	License Agreement between the Company and Hyperion Catalysis International ("Hyperion") dated October 10, 1993 as amended March 15, 1990.
3.4 ⁴	Bylaws, as currently in effect.	10.8 ³	Common Stock Purchase Agreement between the Company and Organon Teknika B.V. ("Organon") dated May 19, 1993.
4.1 ⁷	Form of Specimen Right Certificate.	10.9 ^{3*}	License and Technology Development agreement between the Company and Organon dated May 19, 1993.
4.2 ⁷	Rights Agreement, dated November 6, 1996, between the Company and The First National Bank of Boston.	10.10 ^{3*}	Term Sheet for Consolidation of Research Projects between the Company and Proteinix Corporation dated December 14, 1993.
4.3 ⁹	Note Purchase Agreement between the Company and the purchasers named therein dated as of March 22, 1999.	10.11 ^{3*}	Term Sheet for consolidation of Cancer Research Projects between the Company and Pro-Neuron, Inc. dated December 14, 1993.
4.4 ¹⁰	Securities Purchase Agreement, dated as of January 11, 2000, among Company and the Purchasers listed on Schedule I thereto.	10.12 ³	Form of Indemnity Agreement entered into between the Company and its directors and officers.
4.5 ⁸	Purchase Agreement for the Series B Convertible Preferred Stock between the Company and the purchasers named therein dated as of December 16, 1997.	10.13 ^{3*}	1985 Stock Option Plan, as amended, and related Form of Incentive Stock Option Grant and Form of Nonqualified Stock Option Grant.
10.1 ¹¹	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington North American Equities Fund, Ltd. dated as of February 9, 2001.	10.14 ^{5*}	1994 Stock Option Plan as amended in 1998.
10.2 ¹¹	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington North American Equities Fund, Ltd. dated February 9, 2001.	10.15 ^{5*}	1994 Non-Employee Directors Stock Option Plan, and related Form of Incentive Stock Option Grant.
10.3 ^{3*}	Agreement between the Company and Eisai Co., Ltd. dated May 25, 1990.	10.16 ⁵	Lease Agreement between the Company and W-M 16020 Limited Partnership dated October 5, 1994.
		10.17 ⁵	Agreement for Purchase and Sale of Joint Venture Interest between the Company and Hyperion, dated December 28, 1994.

Exhibit Number	Description of Document
10.18 ^{6*}	Joint Venture Agreement, dated as of November 30, 1995, between Meso Scale Diagnostics, LLC. ("MSD"), Meso Scale Technologies, LLC. ("MST") and the Company.
10.19 ⁶	Limited Liability Company Agreement, dated as of November 30, 1995, between MSD, MST and the Company.
10.20 ^{6*}	IGEN/MSD License Agreement, dated as of November 30, 1995, between MSD and the Company.
10.21 ^{6*}	Indemnification Agreement, dated as of November 30, 1995, between the Company and Jacob Wohlstadter.
10.22 ¹²	Letter Agreement dated November 29, 2000 between Meso Scale Technologies, LLC., Meso Scale Diagnostics, LLC. and IGEN International, Inc.
10.23 ^{15*}	Amendment No.1 to Joint Venture Agreement between Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC., and IGEN International, Inc. dated August 15, 2001.
10.24 ¹⁵	First Amendment of Limited Liability Company Agreement of Meso Scale Diagnostics, LLC. dated August 15, 2001 between IGEN International, Inc. and Meso Scale Technologies, LLC.
10.25 ^{15*}	Amendment No.1 to IGEN/MSD License Agreement dated August 15, 2001 between Meso Scale Diagnostics, LLC. and IGEN International, Inc.
10.26 ¹⁵	MSD/MST Sublicense Agreement dated November 31, 1995 between Meso Scale Diagnostics, LLC. and Meso Scale Technologies, LLC.
10.27 ^{15*}	Amendment No. 1 to MSD/MST Sublicense Agreement dated August 15, 2001 between Meso Scale Technologies, LLC. and IGEN International, Inc.
10.28 ^{15*}	Consulting Agreement between IGEN International, Inc. and Jacob N. Wohlstadter dated November 31, 1996.

Exhibit Number	Description of Document
10.29 ^{15*}	Indemnification Agreement between IGEN International, Inc., Jacob N. Wohlstadter and JW Consulting Services, LLC. dated November 30, 1996.
10.30 ^{15*}	Employment Agreement between Meso Scale Diagnostics, LLC., IGEN International, Inc., Meso Scale Technologies, LLC. and Jacob N. Wohlstadter dated August 15, 2001.
10.31 ^{19*}	Indemnification Agreement between IGEN International, Inc. and Jacob N. Wohlstadter dated October 6, 2001.
10.32 ^{13*}	Amended Restated Promissory Note effective as of July 22, 2000 between Samuel J. Wohlstadter and the Company.
10.33 ^{13*}	Stock Pledge Agreement effective as of July 22, 2000 between Samuel J. Wohlstadter and the Company.
10.34 ^{13*}	Amended Restated Promissory Note effective as of July 22, 2000 between Richard J. Massey and the Company.
10.35 ^{13*}	Stock Pledge Agreement effective as of July 22, 2000 between Richard J. Massey and the Company.
10.36 ^{18*}	IGEN International, Inc. 2001 Broad Based Stock Option Plan.
10.37 ¹⁷	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Private Placement Fund, Ltd. dated December 17, 2001.
10.38 ¹⁷	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated December 17, 2001.
10.39 ¹⁷	Registration Rights Agreement between IGEN International, Inc. and Acqua Wellington Private Placement Fund, Ltd. dated December 17, 2001.
10.40 ¹⁷	Registration Rights Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated December 17, 2001.
10.41 ²²	Common Stock Purchase Agreement between IGEN International, Inc. and Brown Simpson Partners I, Ltd. dated December 26, 2001.
10.42 ²²	Registration Rights Agreement between IGEN International, Inc. and Brown Simpson Partners I, Ltd. dated December 26, 2001.

Exhibit Number	Description of Document
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10.43 ²¹	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Private Placement Fund, Ltd. dated March 8, 2002.
10.44 ²¹	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated March 8, 2002.
10.45 ²¹	Registration Rights Agreement between IGEN International Inc. and Acqua Wellington Private Placement Fund, Ltd. dated March 8, 2002.
10.46 ²¹	Registration Rights Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated March 8, 2002.
10.47 ¹⁴⁺	Amended 1994 Non-Employee Directors' Stock Option Plan dated June 6, 2001.
10.48 ¹⁹⁺	Termination Protection Program.
10.49 ²⁰	Final Order of Judgment issued in IGEN International, Inc. v. Roche Diagnostics GmbH dated February 15, 2002.
99.1 ²³	Meso Scale Diagnostics, LCC. (a Development Stage Company), Financial Statements at December 31, 2001, and for November 30, 1995 (Inception) through December 31, 2001, and Independent Auditors' Report.
23.1 ²³	Consent of Deloitte & Touche LLP.
23.2	Consent of Deloitte & Touche LLP. Filed herewith.

* Denotes management contract or compensatory plan or arrangement.

* Denotes confidential treatment applied.

(1) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended September 30, 1997.

(2) Previously filed as an exhibit to the Company's Annual Report on Form 10-K, as amended, for the fiscal year ended March 31, 1997.

(3) Previously filed as an exhibit to the Registration Statement on Form S-1, as amended (Registration No. 33-72992).

(4) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended November 14, 2000.

(5) Previously filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 1995.

(6) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended December 31, 1995.

(7) Previously filed as an exhibit to the Company's Form 8-A filed December 10, 1996.

(8) Previously filed as an exhibit to the Company's Registration Statement on Form S-3, as amended (Registration No. 333-45355).

(9) Previously filed as an exhibit to the Company's Form 10-K for the fiscal year ended March 31, 1999.

(10) Previously filed as an exhibit to the Company's Form 8-K on January 12, 2000.

(11) Previously filed as an exhibit to the Company's Form 8-K on February 12, 2001.

(12) Previously filed as an exhibit to the Company's Form 8-K on December 12, 2000.

(13) Previously filed as an exhibit to the Company's Form 10-K for the fiscal year ended March 31, 2001.

(14) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended June 30, 2001.

(15) Previously filed as an exhibit to the Company's Form 8-K as amended on September 5, 2001.

(16) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended September 30, 2001.

(17) Previously filed as an exhibit to the Company's Form 8-K on December 19, 2001.

(18) Previously filed as an exhibit to the Company's Registration Statement on Form S-8 (Registration No. 333-76624).

(19) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended December 31, 2001.

(20) Previously filed as an exhibit to the Company's Form 8-K on February 20, 2002.

(21) Previously filed as an exhibit to the Company's Form 8-K on March 15, 2002.

(22) Previously filed as an exhibit to the Company's Registration Statement on Form S-3 (Registration No. 333-76760).

(23) Previously filed as an exhibit to the Company's Form 10-K for the fiscal year ended March 31, 2002.

Directors

Samuel J. Wohlstadter
Chairman and Chief Executive Officer
IGEN International, Inc.

Richard W. Cass, Esquire
Partner
Wilmer, Cutler & Pickering

Richard J. Massey, Ph.D.
President and Chief Operating Officer
IGEN International, Inc.

Anthony Rees, D.Phil.
Director of Science
Synt:em

and
Professorial Research Fellow
University of Bath

Robert R. Salsmans
President and Chief Executive Officer
Diosynth RTP, Inc.

Joop F. Sistermans
Chairman, Supervisory Board
Thuiszorg Kempenstreek
and
Member, Advisory Committee on
Economy, Ecology and Technology,
Ministry of Economic Affairs
The Netherlands

Executive Officers

Samuel J. Wohlstadter
Chairman and Chief Executive Officer

Richard J. Massey, Ph.D.
President and Chief Operating Officer

George V. Migauskys
Vice President, Chief Financial Officer
and Secretary

Corporate Headquarters

16020 Industrial Drive
Gaithersburg, MD 20877
Telephone: (301) 869-9800
Facsimile: (301) 208-3798
Web Site: www.igen.com

Transfer Agent

EquiServe Trust Company
P.O. Box 43010
Providence, RI 02940-3010
Telephone: (781) 575-3400
Web Site: www.equiserve.com

Shareholder Information

Shareholders with questions about their account, stock transfer requirements, lost certificates, change of address and other related matters may contact the transfer agent.

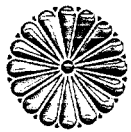
Individuals who would like to receive additional information or have questions regarding IGEN's business activities may call or write to IGEN Investor Relations.

Annual Meeting

The Annual Meeting will be held on Wednesday, August 28, 2002. Questions regarding the Annual Meeting may be directed to IGEN Investor Relations.

Trademarks

IGEN and *ORIGEN* are registered trademarks, and M-SERIES and *PATHIGEN* are trademarks, of IGEN International, Inc.



IGEN International, Inc.

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